Alkohol & Samfund

6.3.2023

Høringssvar til udkast til forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer. (Implementering af dele af delegeret direktiv vedrørende opvarmede tobaksvarer samt andre præciseringer og tekniske justeringer)

Afsender: Alkohol & Samfund
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Generelle bemærkninger

Alkohol & Samfund takker Indenrigs- og Sundhedsministeriet for at give mulighed for at give bemærkninger til lovforslaget om lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer.

Alkohol & Samfund ser et stort behov for at sikre håndhævelse for salg af alkohol både fysisk i butikker og hos onlineforhandlere. Grundlæggende ser vi et behov for styrket forebyggelse af børn og unges alkoholforbrug i form af strukturelle tiltag, herunder alderskontrol for salg af alkohol. Derfor imødekommer vi lovforslaget. Alkohol & Samfund har særligt interesseret sig for det afsnit der omhandler præcisering af kravene til alderskontrol og Sundhedsstyrelsens skilte.

Dog vil Alkohol & Samfund anvende anledning til at gøre opmærksom på, at vi kan konstatere på baggrund af vores mystery shopping undersøgelser, at håndhævelsen af loven for salg af alkohol er utilstrækkelig. Samtidig ser vi danske unge, der drikker meget, tidligt og på en uhensigtsmæssig måde. Derfor er der behov for en yderligere skærpning for at sikre loven bliver håndhævet for salg af alkohol både online og i fysiske butikker.

Til sidst vil Alkohol & Samfund understrege, at én samlet 18-årsgrænse for al salg af alkoholholdige drikkevarer med en alkoholvolumenprocent på 1,2 eller derover, vil være et effektivt tiltag for at gøre det nemmere for detailhandlen at håndhæve aldersgrænserne for salg af alkohol, samt et vigtigt tiltag for at udskyde danske børn og unges alkoholdebut

Tekstnære bemærkninger

Kapitel 2.2.3 Præcisering af krav til alderskontrol og Sundhedsstyrelsens skilte

Effektiv alderskontrol ved fysiske salgssteder

"Det foreslås, at på fysiske salgssteder vil alderskontrollen skulle ske ved at efterspørge gyldig billedlegitimation, hvis sælgeren er i tvivl om, hvorvidt kunden opfylder aldersgrænserne." (s. 16)

Alkohol & Samfunds mystery shopping undersøgelser viser at børn og unge helt ned til 13 år kan købe alkohol i kiosker, supermarkeder og på tankstationer. Ved test af 16-årsgrænsen kunne de

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unge købe alkohol i 79% af tilfældene i 2020, mens de unge, der testede 18-årsgrænsen kunne købe alkohol i 65% af tilfældene.[1] Derfor mener vi, at lovgivningen ikke er skærpet nok, hvis der ønskes effektiv håndhævelse. I det svenske Systembolaget er det lovpligtigt, at alle kunder under 25 år viser billedelegimitation[2]. I Danmark bør fysiske salgssteder pålægges altid at spørge kunder, der er eller ser ud til at være under 25 år om gyldig legitimation ved salg af produkter, der har en aldersbegrænsning, herunder alkoholholdige varer.

Effektivt alderskontrolsystem

"Ved markedsføring af produkterne online foreslås det, at der skal etableres og drives et generelt alderskontrolsystem. Alderskontrolsystemet skal sikre, at kunden ikke kan gennemføre køb af produkterne uden først utvetydigt at tilkendegive, at kunden opfylder aldersgrænserne." (s. 16)

Alkohol & Samfund gør opmærksom på, at der allerede findes effektive metoder til at verificere alder ved onlinesalg af alkohol fx ved brug af MitID. I Alkohol & Samfunds mystery shopping undersøgelse[3] af salg af alkohol fra onlineforhandlere, var Rema1000 den eneste forhandler med et alderskontrolsystem, der effektivt forhindrede mindreårige i at købe alkohol online. Rema1000 anvendte MitID (dengang NemID), der kontrollerede køberens alder og afviste gennemførelse af købet. Derfor opfordrer vi til, at onlineforhandlere af alkohol pålægges at anvende MitID ved køb af alkohol, for effektivt at forhindre onlinesalg af alkohol til mindreårige.

Derfor finder Alkohol & Samfund det særligt problematisk, at følgende bemærkninger til §2, stk. 3 og §3, til nr. 3 (s. 44-45), da det ikke sikrer, at aldersverificeringen foregår effektivt:

"Ved utvetydig tilkendegivelse skal forstås, at kunden direkte skal forholde sig til og foretage en aktiv handling for at verificere sin alder. Det er således som udgangspunkt ikke tilstrækkeligt, hvis kunden alene skal acceptere de generelle handelsbetingelser, som indeholder et krav om at kunden skal være fyldt 18 år. Det betyder f.eks. at accept af generelle handelsbetingelser og bekræftelse af, at kunden er fyldt 18 år skal meddeles separat"

"Alderskontrolsystemet skal sikre, at kunden ikke kan gennemføre køb af produkterne uden først utvetydigt at tilkendegive, at kunden opfylder aldersgrænsen.

Der er ikke krav til den konkrete metode, hvorpå kunden tilkendegiver sin alder (pop up, afkrydsning eller andet). Alderskontrolsystemet kan f.eks. bestå af en fast procedure for, at kunden ved køb af produktet vil blive præsenteret for et spørgsmål om, hvorvidt kunden er over 16 år. Denne tilgang bygger på den aktuelle praksis på området samt forslaget til et alderskontrolsystem, når elektroniske cigaretter og genopfyldningsbeholdere med nikotin markedsføres til danske forbrugere ved hjælp af fjernsalg på tværs af grænser, jf. bemærkningerne til § 15, stk. 2, i lov om elektroniske cigaretter,

[1] Alkohol & Samfund (2021). Solgt ulovligt. https://alkohologsamfund.dk/files/media/document/Solgt%20ulovligt.pdf
[2] https://www.omsystembolaget.se/salja-med-ansvar/ansvarsfull-forsaljning/skydda-unga-fran-alkohol/darfor-ber-vi-om-legg/
[3] Alkohol & Samfund (2021). Solgt ulovligt. https://alkohologsamfund.dk/files/media/document/Solgt%20ulovligt.pdf

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jf. Folketingstidende 2015-16, tillæg A, L 144 som fremsat, side 44. Ved utvetydig tilkendegivelse skal forstås, at kunden direkte skal forholde sig til og foretage en aktiv handling for at verificere sin alder. Det er således som udgangspunkt ikke tilstrækkeligt, hvis kunden alene skal acceptere de generelle handelsbetingelser, som indeholder et krav om, at kunden skal være fyldt 16 år. Det betyder f.eks. at accept af generelle handelsbetingelser og bekræftelse af, at kunden er fyldt 16 år skal meddeles separat.

En deaktiveret ordre på baggrund af betalingskortet, f.eks. ved brug af korttyper, der kun kan udstedes til personer under 18 år, er ikke tilstrækkeligt i sig selv til at opfylde kravene om utvetydig tilkendegivelse. Det er heller ikke tilstrækkeligt i sig selv, hvis købet ophæves eller ordren ikke bliver leveret, idet kunden i disse tilfælde ikke har afgivet en tilkendegivelse. (s. 47-48)

Med overstående krav til "utvetydig tilkendegivelse af alder" er det meget nemt at omgå aldersgrænserne. Det har Alkohol & Samfund netop bevist ved tidligere undersøgelser af online salg af alkohol.

Opmærksomhed på tredjeparters salg af alkohol fx leveringsbud

Bemærkninger til lovforslagets enkelte bestemmelser til §3, til nr. 4: "Det påhviler den person eller virksomhed m.v. der erhvervsmæssigt markedsfører produkterne på hjemmesider, profiler, apps m.v. at sikre, at der ikke sælges alkoholholdige drikkevarer med en alkoholvolumenprocent på 1,2 eller derover til børn og unge under 16 år i strid med reglerne i § 2, stk. 1, og den foreslåede § 2 a, stk. 4, i lov om forbud mod salg af tobak og alkohol til personer under 18 år." (s. 48)

Alkohol & Samfund gør opmærksom på, at dette er væsentligt, da det kan være uklart ved køb gennem tredjepart fx brug af udbringningsservices (Fx Wolt.dk eller Snackreload.dk). Det skal være tydeligt at udbringningsvirksomheden også skal verificere alder – gerne elektronisk, da køb foregår "online" via app eller hjemmeside. Det opfordres til at Sikkerhedsstyrelsen fører tilsyn med disse typer af virksomheder.

Sikre at Sikkerhedsstyrelsens kan føre effektiv kontrol af håndhævelsen for salg af alkohol

Bemærkninger til lovforslagets enkelte bestemmelser til §3, til nr. 10: "Det fremgår af § 2 b, stk. 1, i lov om forbud mod salg af tobak og alkohol til personer under 18 år, at Sikkerhedsstyrelsen fører kontrol med, at kravene i §§ 1-2 a og regler udstedt i medfør af § 2 a, stk. 6, overholdes. Af lovens § 2 b, stk. 2, fremgår det, at Sikkerhedsstyrelsens repræsentanter til enhver tid uden forevisning af legitimation har adgang til forhandleres butikslokaler med henblik på at kontrollere overholdelsen af §§ 1-2 a og regler udstedt i medfør af § 2 a, stk. 6. Af lovens § 2 b, stk. 3, fremgår det, at Sikkerhedsstyrelsens repræsentanter mod behørig legitimation og uden retskendelse kræve kan at få meddelt alle oplysninger fra detailforhandlere og købere af alkohol, tobaksvarer, tobakssurrogater og urtebaserede rygeprodukter, der er nødvendige for kontrollen efter stk. 1." (s. 55)

"Efter § 15 a, stk. 1, i kapitel 6, i samme lov kan indenrigs- og sundhedsministeren bemyndige Sikkerhedsstyrelsen til at føre kontrol med, at kravet i § 15, stk. 1, overholdes. Det følger af bestemmelsens stk. 2, at indenrigs- og sundhedsministeren kan fastsætte regler om adgangen til at påklage afgørelser, der er truffet i henhold til bemyndigelsen efter stk. 1, herunder at afgørelserne ikke skal kunne påklages. Af samme bestemmelses stk. 3 følger, at ministeren endvidere kan fastsætte regler om

udøvelsen af de beføjelser, som Sikkerhedsstyrelsen bliver bemyndiget til at udøve efter stk. 1." (s. 17)

Sikkerhedsstyrelsens kontrol med overholdelsen af aldersgrænser burde være ent væsentlig faktor for at begrænse ulovligt salg af alkohol til mindreårige. Men Sikkerhedsstyrelsens kontroller har vist sig ikke at være en effektiv metode til at sikre fysiske salgssteders håndhævelse af loven.

Alkohol & Samfund har aktivt testet om fysiske salgssteder håndhæver loven om salg af alkohol ved mystery shopping. Mystery shopping er en metode, hvor 13-15-årige tester køb af alkohol for 16-årsgrænsen og 16-17-årige tester køb af alkohol for 18-årsgrænsen.

Sikkerhedsstyrelsen har ikke hjemmel til at foretage mystery shopping. Ud af de 550 alderskontroller Sikkerhedsstyrelsen foretog i 2020, observerede styrelsen kun to tilfælde af ulovligt salg af alkohol til mindreårige[4]. I 2020 fandt Alkohol & Samfund i en stikprøve til sammenligning brud i 82 ud af 110 tilfælde[5].

Hvis man reelt ønsker at sikre, at salgssteder ikke sælger alkohol ulovligt til børn og unge, så bør Sikkerhedsstyrelsen sikres hjemmel til at udføre mystery shopping for at skabe en effektiv kontrol, der sikrer håndhævelse af loven mere effektivt.

Mystery shopping har en dokumenteret effekt i andre europæiske lande til øget håndhævelse af loven for salg af alkohol. Derfor vurderer Alkohol & Samfund, at mystery shopping kan være et nyttigt initiativ til øge håndhævelsen af loven og reducere ulovligt salg af alkohol til mindreårige i Danmark. I Norge har mystery shopping medvirket til, at ulovligt salg af alkohol er faldet fra 40 % i 2007 til 18,5 % i 2019[6]. Salget af alkohol til unge under aldersgrænserne er altså mere end halveret i løbet af de 12 år, som Juvente har gennemført mystery shoppingen. Ligeledes i Schweiz har vedvarende mystery shopping ændret ID-kulturen. Aldersgrænserne for salg af alkohol ligner de danske med 16 år for salg af øl og vin, samt 18 år for salg af spiritus. Da de første mystery shoppere forsøgte at købe alkohol i 2000, blev de kun spurgt om ID i 3,5 % af købsforsøgene[7]. I 2019 blev mystery shoppere bedt om at vise billede-ID i 80 % af købsforsøgene[8]. I Schweiz er mystery shopping indskrevet i loven og opgaven ligger hos den Schweiziske Føderale Toldadministration. Mystery shoppingen bliver varetaget af både private institutioner og myndighederne efter en procedure, der svarer til den Alkohol & Samfund anvender.

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[4] Tal indhentet fra Sikkerhedsstyrelsen i november 2020

[5] Alkohol & Samfund (2021). Solgt ulovligt. https://alkohologsamfund.dk/files/media/document/Solgt%20ulovligt.pdf

[6] Skjenkekontrollen, 2019. *Kontrollrapport 2019.* Oslo: Juvente; 2019. s. 1-20. Hentet fra https://om.skjenkekontrollen.no/wp-content/uploads/2020/03/Kontrollrapport-2019-ferdig.pdf

[7] Europa Kommissionen, 2012. *Eyes on Ages A research on alcohol age limit policies in European Member States. Legislation, enforcement and research.* Holland: Dutch Institute for Alcohol Policy. s. 51. Hentet fra https://ec.europa.eu/health/sites/health/files/alcohol/docs/eyes_on_ages_report_en.pdf

[8] Swiss Customs Administration, 2020. *"Test purchases"*. Hentet d. 9.12.2020 fra https://www.ezv.admin.ch/ezv/en/home/topics/alcohol/praevention_jugendschutz/praeventionsinstrumente/testkae-ufe.html

Indenrigs- og Sundhedsministeriet

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København den 06.03.2023

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British American Tobacco Denmark A/S takker for muligheden for at afgive høringssvar på høringen vedrørende;

Udkast til forslag til lov om ændring af lov om tobaksvarer (Implementering af dele af delegeret direktiv vedrørende opvarmede tobaksvarer m.m.)

Med venlig hilsen

Anders Preben Burlund

Government Affairs Manager
British American Tobacco Denmark A/S

BRITISH AMERICAN TOBACCO DENMARK A/S & NICOVENTURES TRADING LIMITEDS SVAR TIL SUNDHEDSMINISTERIET

KOMMENTARER ANG. NATIONAL IMPLEMENTERING AF DELEGERET DIREKTIV OM OPVARMEDE TOBAKSVARER OG ANDEN REGULERING AF NIKOTIN- OG RØGFRI TOBAKSVARER

I

LOVFORSLAGET OM ÆNDRING AF LOVEN OM TOBAKSVARER M.V., LOVEN OM ELEKTRONISKE CIGARETTER M.V., LOVEN OM RØGFRI MILJØER OG DIVERSE ANDRE LOVE.

6 MARTS 2023

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1. INTRODUKTION

1.1 Dette anbringende fra British American Tobacco Denmark A/S (driver også virksomhed under navnet House of Prince A/S) ("**BAT Denmark**") og Nicoventures Trading Limited ("**Nicoventures**") (dette "**Svar**") reagerer på en høring om udkastet til lovforslaget om ændring af loven om tobaksvarer m.v., loven om elektroniske cigaretter m.v., loven om forbud mod salg af tobak og alkohol til personer under 18 år og loven om røgfri miljøer (under ét, "**Lovforslag**").

1.2 Dette dokument reagerer især på den foreslåede implementering af det delegerede direktiv 2022/2100/EU af 29. juni 2022 ("**Delegeret direktiv")**[1] vedrørende opvarmede tobaksvarer ("**THP'er**") i dansk lovgivning samt visse forslag vedrørende alderskontrol for køb af tobaksvarer og nikotinprodukter.

1.3 BAT Denmark og Nicoventures er medlemmer af koncernen British American Tobacco ("**BAT**"). Nicoventures er involveret i udviklingen og kommercialiseringen af BAT's udvalg af alternative tobaksvarer og nikotinprodukter. BAT's hovedfokus var historisk set traditionelle tobaksvarer, men koncernen fokuserer i stigende grad på udvikling og kommercialisering af ikke-brændbare alternativer til konventionelle cigaretter til voksne rygere, der ellers ville fortsætte med at ryge. Dette omfatter udvikling og salg af THP'er både globalt og inden for EU, herunder i Danmark. BAT Denmark er ansvarlig for distribution af BAT's THP'er i Danmark.

1.4 BAT Denmark og Nicoventures omtales samlet som "**BAT**" nedenfor.

1.5 **Det delegerede direktiv**

1.6 Det delegerede direktiv ændrer og supplerer direktiv 2014/40/EU af 3. april 2014 ("**Tobaksvaredirektivet**" eller "**TPD**") og blev offentliggjort af Europa-Kommissionen ("**Kommissionen**") i EU-Tidende d. 3. november 2022. Det delegerede direktiv ændrer artikel 7, stk. 12 i tobaksvaredirektivet således:

"Andre tobaksvarer end cigaretter og rulletobak samt opvarmede tobaksvarer er undtaget fra forbuddene i stk. 1 og 7. Europa-Kommissionen kan vedtage delegerede retsakter i overensstemmelse med artikel 27 med formål at kunne trække denne undtagelse tilbage for en bestemt produktkategori, hvis der sker en væsentlig ændring i forholdene som fastsat i en rapport fra Kommissionen.

[1] Europa-Parlamentets og Rådets direktiv (EU) af 29. juni 2022 om ændring af Europa-Parlamentets og Rådets direktiv 2014/40/EU om ophævelse af visse undtagelser for opvarmede tobaksvarer, C(2022) 4367 findes her: https://eur-lex.europa.eu/legal-content/DA/TXT/PDF/?uri=CELEX:32022L2100&from=EN

I første afsnit forstås ved "opvarmet tobaksvare" en ny kategori af tobaksvarer, der opvarmes for at frembringe en emission indeholdende nikotin og andre kemikalier, som derefter inhaleres af brugeren/brugerne, og som afhængigt af deres karakteristika er røgfrie tobaksvarer eller røgtobak."

1.7 Som følge heraf gør det delegerede direktiv følgende:

1.7.1 Opretter en ny produktkategori, der ikke var forudset i tobaksvaredirektivet og derfor ikke blev defineret herunder, dvs. et "*opvarmet tobaksprodukt*"; og

1.7.2 Fjerner samtidig for denne nye produktkategori undtagelsen fra forbuddet mod at markedsføre tobaksvarer med en kendetegnende aroma (artikel 7, stk. 1 i tobaksvaredirektivet) eller tobaksvarer, der indeholder aromastoffer i deres bestanddele (artikel 7, stk. 7 i tobaksvaredirektivet).

1.8 Det delegerede direktiv ændrer også artikel 11, stk. 1 i tobaksvaredirektivet, og fjerner dermed muligheden for, at medlemsstaterne undtager THP'er til rygning fra forpligtelsen til at bære informationsmeddelelsen og kombinerede sundhedsadvarsler (artikel 9, stk. 2 og 10 i tobaksvaredirektivet). Med andre ord fordrer det delegerede direktiv, at medlemsstaterne stiller disse krav for THP'er til rygning.

1.9 Det delegerede direktiv blev vedtaget på grundlag af delegerede beføjelser, som er tildelt Kommissionen i artikel 7, stk. 12, og artikel 11, stk. 6 i tobaksvaredirektivet for at fjerne ovennævnte undtagelser for etablerede kategorier af tobaksvarer, når der indtræffer en "*væsentlig ændring i forholdene*". Eksistensen af denne "*væsentlige ændring i forholdene*" beror på, at Kommissionen kan påvise, at visse økonomiske fakta/betingelser er til stede, herunder at markedsandelen for THP'er er over 2,5 % af det samlede salg af tobaksvarer i EU. I rapporten, der blev vedtaget den 15. juni 2022 ("**Kommissionens rapport**"), hævder Kommissionen, at den har fastslået, at disse økonomiske fakta/betingelser er til stede.[2]

1.10 Den 16. november 2022 indgav Nicoventures og andre BAT-enheder en ansøgning om ophævelse af det delegerede direktiv ved EU-Domstolen ("**EU-Domstolen**").[3] Den 13. december 2022 anfægtede Nicoventures og andre BAT-forretningsenheder også indirekte det delegerede direktiv over for High Court of Ireland og indgav en anmodning om at få sagen indbragt ved EU-Domstolen.[4] Begge disse sager er igangværende.

1.11 **Lovforslaget**

1.12 Lovforslaget foreslår implementering af det delegerede direktiv ved:

1.12.1 Indsættelse af en ny definition af THP'er i § 2, stk. 31 i loven om tobaksvarer m.v.

1.12.2 Ændring af §§ 14, 15 og 16 i loven om tobaksvarer m.v. for at inkludere THP'er i de eksisterende forbud mod markedsføring af tobaksvarer med en kendetegnende aroma eller tobaksvarer, der indeholder aromastoffer i deres bestanddele.

1.13 Som forklaret nærmere i dette svar mener vi, at det delegerede direktiv er ugyldigt i henhold til EU-lovgivningen og derfor ikke bør implementeres i den danske lovgivning – og bestemt ikke så længe de ovennævnte igangværende retssager vedr. det delegerede direktiv endnu ikke er afgjort ved domstolene. Vi mener også, at de forslag, der implementerer det delegerede direktiv, med større sandsynlighed vil skade folkesundheden end at gavne den.

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2 Rapporten fra Kommissionen, der fastslår en væsentlig ændring af forholdene for opvarmede tobaksvarer i overensstemmelse med direktiv 2014/40/EU, COM(2022) 279 af 15. juni 2022, findes her: https://ec.europa.eu/transparency/documents-register/detail?ref=COM(2022)279&lang=en=en

3 Sag T-706/22, offentliggjort i EU-Tidende den 16. januar 2023, se her: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62022TN0706&qid=1673874316710

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1.14 Lovforslaget indeholder også tydeliggørelse af kravene til alderskontrol ved salg af tobaksvarer og nikotinprodukter både på fysiske salgssteder og online. Som forklaret nedenfor støtter vi disse tiltag fuldt ud.

2. SAMMENFATNING

2.1 BAT er imod den foreslåede implementering af det delegerede direktiv af følgende grunde:

2.1.1 Kommissionen har ulovligt overskredet omfanget af de delegerede beføjelser, som den er blevet tillagt. I særdeleshed:

(A) Ved at regulere en ny kategori af tobaksvarer, dvs. THP'er, som aldrig er blevet taget i betragtning af EU-lovgiveren, behandler det delegerede direktiv et "*væsentligt element*" i betydningen jf. artikel 290, stk. 1, i traktaten om Unionens funktionsmåde ("**TEUF**"), som ikke kunne været blevet delegeret til Kommissionen. Bekymringen blev rejst af fire medlemslande, da Kommissionen første gang kom med et udkast til det delegerede direktiv,[5] og det indrømmes i al væsentlighed i Kommissionens Begrundelse, der ledsager det delegerede direktiv.[6]

(B) Det delegerede direktiv introducerer en ny "*særlig produktkategori*" i henhold til tobaksvaredirektivet, dvs. THP'er, det overskrider Kommissionens delegerede beføjelser og krænker de generelle EU-lovprincipper om retssikkerhed og legitime forventninger. Kommissionen har kun beføjelse til at ændre reglerne for en eksisterende produktkategori. Den kan ikke oprette en ny produktkategori.

(C) Den nye "*særlige produktkategori"*, der introduceres af det delegerede direktiv, er ikke i overensstemmelse med systemet for tobaksvaredirektivet. Det er ikke muligt, at THP'er på samme tid er en "*ny kategori af tobaksvarer*" og *en* "*særlig produktkategori*" og omfatter både "*røgfri tobaksvarer*" og "*røgtobak*", da disse er gensidigt udelukkende.

(D) Kommissionens tilgang til vurdering af tilstedeværelsen af en "*væsentlig ændring i forholdene*" er behæftet med fejl og overskrider den tekniske opgave, der er delegeret til den, især fordi den vurderer markedsandele på "*antal cigaretter*" i modsætning til tobaksvægten, til trods for at en enkelt opvarmet tobakspind kun indeholder ca. halvt så meget tobak som en cigaret.

2.1.2 Det delegerede direktiv er derfor ugyldigt i henhold til EU-lovgivningen og bør ikke overføres til den danske lovgivning,da enhver lov der implementerer det Delegerede directiv ind i gældende dansk lov, vil være ugyldig. Især ikke givet de forhold, hvor det delegerede direktiv er genstand for igangværende retssager.

2.2 Såfremt Sundhedsministeriet – uanset ovenstående – mener, at det bør fortsætte med at overføre det delegerede direktiv til dansk lovgivning, mener vi – uden at det berører ovenstående punkter – at Sundhedsministeriet bør anvende et passende sprog til at definere THP'er og anerkender forskellen mellem røgfri tobaksvarer og røgtobak, og at de skærpede mærkningskrav i artikel 9, stk. 2 og artikel 10 i tobaksvaredirektivet alene gælder for THP'er "*i det omfang, de er røgtobak*".

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5 18. møde i gruppen af eksperter i tobakspolitik den 9. februar 2022 kan ses her https://ec.europa.eu/transparency/expert-groups-register/screen/meetings/consult?lang=en&meetingId=38075&fromExpertGroups=true

6 Stk. 2 i Begrundelsen, der ledsager Europa-Parlamentets og Rådets direktiv (EU) .../... om ændring af Europa-Parlamentets og Rådets direktiv 2014/40/EU om ophævelse af visse undtagelser for opvarmede tobaksvarer, C(2022) 4367 endelig udgave af 29. juni 2022, findes her: https://data.consilium.europa.eu/doc/document/ST-10815-2022-INIT/en/pdf

2.3 Implementering af det delegerede direktiv i lovforslag vil sandsynligvis have en negativ indvirkning på folkesundheden. I særdeleshed:

2.3.1 De førende sundhedsmyndigheder har anerkendt den reducerede risikoprofil for THP'er sammenlignet med brændbare tobaksvarer.

2.3.2 De foreslåede aromabegrænsninger vil påvirke voksne rygere negativt og vil sandsynligvis medføre utilsigtede konsekvenser, da en reduktion af forbrugerudvalget af ikke-brændbare produkter kan føre til, at voksne genoptager rygning eller opsøger det uregulerede ulovlige marked, hvis deres foretrukne smagsstoffer ikke længere er til rådighed.

2.3.3 Ved at anvende regler på THP'er, der er møntet på brændbare tobaksvarer, formidles det vildledende budskab, at de risici, der er forbundet med THP'er, er de samme som dem, der er forbundet med indtagelse af brændbare tobaksvarer. Det har den virkning, at brugen af mere farlige brændbare tobaksvarer bibeholdes, og det undergraver deres potentiale til at reducere skader som følge af tobaksrygning.

2.3.4 I sidste ende vil en ubalanceret lovgivning forhindre THP'er i at opnå deres potentiale for at reducere tobaksskader.

2.4 På baggrund af ovenstående, og hvis Sundhedsministeriet vælger at overføre det delegerede direktiv til dansk lovgivning, bør det vente med at gøre det til den senest mulige dato (dvs. 23. juli 2023).

2.5 BAT støtter de foreslåede præciseringer af kravene til alderskontrol ved salg af tobaksvarer og nikotinprodukter ved køb.

3. DET DELEGEREDE DIREKTIV OVERSKRIDER PÅ ULOVLIG VIS DE DELEGEREDE BEFØJELSER

3.1 Lovvalg

3.2 Artikel 290, stk. 1 i TEUF indeholder følgende (understregning tilføjet):

"*Kommissionen kan i en lovgivningsmæssig retsakt få delegeret beføjelse til at vedtage almengyldige ikke-lovgivningsmæssige retsakter, der supplerer eller ændrer visse ikke-væsentlige bestemmelser i den lovgivningsmæssige retsakt.*

De lovgivningsmæssige retsakter afgrænser udtrykkeligt delegationens formål, indhold, omfang og varighed. De væsentlige bestemmelser på et område er forbeholdt den lovgivningsmæssige retsakt og kan derfor ikke være omfattet af delegation."

3.3 I henhold til EU-Domstolens retspraksis er et element "væsentligt" i betydningen af den anden sætning i artikel 290, stk. 1 i TEUF, såfremt det fordrer politiske valg der falder inden for EU-lovgivningens ansvarsområder, fordi det kræver, at de pågældende modstridende interesser skal afvejes ud fra en række vurderinger. Der skal endvidere tages hensyn til det pågældende felts karakteristika og særlige egenskaber.

3.4 EU-domstolens retspraksis fastslår endvidere, at de delegerede beføjelser skal være præcist afgrænset i den lov, der tildeler de delegerede beføjelser, og at afgrænsningerne ikke kan overlades til Kommissionens eget skøn. Dette princip er formuleret således i Kommissionens egne retningslinjer om delegerede love: *"Lovgiveren skal udtrykkeligt og præcist beskrive de beføjelser, den har til hensigt at delegere til Kommissionen"* og *"upræcise formuleringer [...] er ikke mulige*.[7]" Derfor skal Kommissionens beføjelser fastslås og fortolkes præcist, ikke upræcist, og fortolkes på omfattende vis.

[7] Delegerede love – Vejledning til Kommissionens tjenester, 24. juni 2011, SEC(2011) 588, stk. 52 findes her: https://ec.europa.eu/transparency/documents-register/detail?ref=SEC(2011)855&lang=en

3.5 **Ved at regulere ny kategori af tobaksvarer regulerer Kommissionen et "væsentligt element" og træffer ulovlige politiske valg**

3.6 Som det fremgår af selve det delegerede direktiv, er THP'er "*nye kategorier af tobaksvarer*" i henhold til artikel 2, stk. 14 i tobaksvaredirektivet, hvilket betyder, at de er markedsført efter den 19. maj 2014. THP'er kan derfor ikke betragtes som en af de eksisterende "produktkategorier" i henhold til artikel 7, stk. 12 og artikel 11, stk. 6 i tobaksvaredirektivet.

3.7 EU-lovgiveren kunne ikke på lovlig vis have delegeret beføjelser til Kommissionen til at regulere en ny kategori af tobaksvarer. Lovgiveren ville i den forbindelse have delegeret beføjelserne til at regulere et nyt produkt, som EU-lovgiveren aldrig havde taget i betragtning, og som havde en helt anden risikoprofil end de etablerede tobaksvarekategorier (se yderligere i afsnit [4.16-4.20] nedenfor). Ifølge enhver analyse omfatter dette politiske valg hinsides de "*ikke-væsentlige elementer*", der kan behandles via delegeret lovgivning.

3.8 Fire medlemsstater gjorde tobakssekspertgruppen opmærksom på dette, da Kommissionen udgav første udkast til det delegerede direktiv.[8] I henhold til disse medlemsstater gælder der følgende for det delegerede direktiv:

3.8.1 *"har en dybdegående indvirkning på området med opvarmede tobaksvarer"* og introducerer en *"kompleks og omfattende reform";* og

3.8.2 *"overskrider den delegerede beføjelse i henhold til direktiv 2014/40/EU og omfatter væsentlige elementer, der er forbeholdt de europæiske lovgivere".*

3.9 Kommissionen har aldrig reageret på denne bekymring – hverken i tobakssekspertgruppen eller i Begrundelsen, der ledsager det delegerede direktiv.

3.10 Som nævnt ovenfor fordrer den etablerede retspraksis, at der ved vurderingen af, om et element er "væsentligt", skal tages hensyn til det "*pågældende felts karakteristika og særlige egenskaber*". I den forbindelse skal det bemærkes, at artikel 168, stk. 5, i TEUF udtrykkeligt udelukker *"nogen form for harmonisering"* med hensyn til *"beskyttelse af folkesundheden i forbindelse med tobak"*, hvilket tydeligt påpeger nye kategorier af tobaksvarers "*væsentlige*" karakter. Denne begrænsning af EU's beføjelser kræver, at delegerede beføjelser på dette område ikke kan fortolkes i bredt omfang. Selvom vi har forståelse for, at artikel 114 i TEUF er det retsgrundlag, der anvendes for tobaksvaredirektivet, ville det være højst bemærkelsesværdigt, hvis Kommissionen i kraft af en delegeret lov kunne påvirke en medlemsstats evne til at godkende salg af visse tobaksvarer med nedsatte risikoprofiler (i forhold til cigaretter) som et instrument i en folkesundhedspolitik. Hvis dette var muligt, ville en sådan traktats sikkerhedsforanstaltning i henhold til medlemsstaternes kompetence være værdiløs.

3.11 Konklusionen om, at indførelsen af nye regler for nye produkter ikke kan ske ved delegeret handling, fremgår ligeledes af ordlyden af artikel 7, stk. 12, og artikel 11, stk. 6 i tobaksvaredirektivet, der fastslår, at de delegerede beføjelser kan benyttes til "*en bestemt produktkategori*".

3.12 Begrebet "*bestemt produktkategori"*, som anvendes i artikel 7 i tobaksvaredirektivet, svarer til de veletablerede "kategorier", der er anført i artikel 2, stk. 14, litra a), i tobaksvaredirektivet. Denne bestemmelse definerer "*ny kategori af tobaksvarer*" som ethvert tobaksprodukt:

3.12.1 bortset fra "*cigaretter, rulletobak, pibetobak, vandpibetobak, cigarer, cigarilloer, tyggetobak, tobak der indtages nasalt eller tobak der indtages oralt*", som

3.12.2 også er "*nyt*", dvs. det er første gang markedsført efter 19. maj 2014.

3.13 I medfør af tobaksvaredirektivets klare ordlyd skal begrebet "*bestemt produktkategori*" derfor opfattes særskilt fra begrebet "*ny kategori af tobaksvarer*". Disse er gensidigt udelukkende

[8] 18. møde i gruppen af eksperter i tobakspolitik den 9. februar 2022

produktgrupper, da artikel 2, stk. 14 udtrykkeligt definerer "ny kategori af tobaksvarer" som modsætningen til "*særlige produktkategorier*".

3.14 Dette bekræftes yderligere af artikel 28, stk. 2 i tobaksvaredirektivet, som opremser de elementer, som Kommissionen skal være særlig opmærksom på i sin rapport om anvendelsen af tobaksvaredirektivet. Artikel 28, stk. 2 skelner mellem markedsudviklinger vedrørende nye kategorier af tobaksvarer (artikel 28, stk. 2, litra b)) og markedsudviklinger, der udgør en væsentlig ændring i forholdene (artikel 28, stk. 2, litra c)). Dette understreger igen tydeligt, at nye kategorier af tobaksvarer adskiller sig fra produktkategorierne i artikel 7, stk. 12 og artikel 11, stk. 1 i tobaksvaredirektivet, og som er underlagt de delegerede beføjelser.

3.15 Det bekræftes yderligere af prøven i artikel 28, stk. 2 i tobaksvaredirektivet på, om der er sket en "*væsentlig ændring i forholdene*". Den første alternative betingelse for at tale om en væsentlig ændring i forholdene er, at salgsmængderne for produktkategorien er steget med mindst 10 % i mindst fem medlemslande. Men for nye kategorier af tobaksvarer som f.eks. THP'er vil startniveauet pr. definition være nul, hvilket gør det matematisk umuligt at fastslå en stigning på 10 %. Selv hvis man ignorerer denne matematiske virkelighed ved at tage udgangspunkt i et tidspunkt kort efter lanceringen af den nye kategori af tobaksvarer på markedet, vil enhver beregning, der tager udgangspunkt i et meget lavt grundtal, resultere i enorme procentstigninger, selv om stigningen i absolutte tal er meget begrænset. Det gør denne betingelse praktisk talt ubrugelig. Dette fremgår af Kommissionens rapport, der angiveligt viser stigninger på over 999 % i salget af THP i visse medlemslande beregnet ud fra meget lave grundværdier i 2018.[9] Det er absurd, og det kan ikke have været hensigten med EU-lovgivningen.

3.16 Denne fortolkning bekræftes også af tobaksvaredirektivets lovhistorik. I Begrundelsen til Kommissionens forslag til tobaksvaredirektivet står der:

"Nye kategorier af tobaksvarer er produkter, der indeholder tobak, som ikke falder inden for nogen af de etablerede produktkategorier (f.eks. cigaretter, rulletobak, pibetobak, vandpibetobak, cigarer, cigarilloer, tyggetobak, tobak der indtages nasalt eller tobak der indtages oralt), og som introduceres på markedet efter direktivets ikrafttræden. [...][10]" (understregning tilføjet)

3.17 Konklusionen er klar. Den delegerede beføjelse i artikel 7, stk. 12, og artikel 11, stk. 6, påtænker, at Kommissionen kan fjerne visse undtagelser, hvis nogle af de etablerede kategorier skulle nå et vist salgsniveau hos forbrugere, som udløser tærsklen *for* "*væsentlig ændring i forhold*" som defineret i artikel 2, stk. 28 i tobaksvaredirektivet, f.eks. cigarilloer eller cigarer. Som fordret af artikel 290, stk. 1 i TEUF blev den politiske beslutning om at fjerne disse undtagelser i tilfælde af øget salg af disse etablerede kategorier i forhold til andre tobaksvarer (dvs. det væsentlige element) taget af EU-lovgiveren ved optagelse af tobaksvaredirektivet. Den delegerede beføjelse defineres også præcist af lovgiveren som fordret af artikel 290, stk. 1 i TEUF. Denne delegerede beføjelse kan dog ikke anvendes til at regulere nye produkter, som lovgiveren aldrig specifikt har taget i betragtning – som ikke er en "*særlig produktkategori*" i henhold til artikel 7, stk. 12, og artikel 11, stk. 6 i tobaksvaredirektivet – og som har en fundamentalt forskellig risikoprofil fra de etablerede tobaksvarekategorier.

3.18 Begrundelsen, der ledsager det delegerede direktiv, indeholder meget lignende argumenter:

"*Artikel 7, stk. 12, og artikel 11, stk. 6, i direktiv 2014/40/EU giver ikke Kommissionen nogen skønsmargen, men giver Kommissionen den tekniske opgave at fastslå, om der er*

9 Kommissionens rapport, tabel 1.

10 Punkt 3.6 i Begrundelse til forslag til Europa-Parlamentets og Rådets direktiv om tilnærmelse af medlemsstaternes love, forordninger og administrative bestemmelser vedrørende fremstilling, præsentation og salg af tobak og relaterede produkter, KOM(2012)788 endelig udgave af 19.12.2012 findes her: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014L0040

sket en væsentlig ændring i forholdene for en bestemt produktkategori, [...]. Den politiske beslutning om at forbyde markedsføring af tobaksvarer med kendetegnende aromaer med henblik på at opnå et højt sundhedsbeskyttelsesniveau, især for unge, er allerede foretaget i medfør af EU-lovgiveren i selve direktiv 2014/40/EU (se også punkt 19 og 26 i direktivet)."[11] (understregning tilføjet)

3.19 Det er korrekt, at artikel 7, stk. 12, og artikel 11, stk. 6 ikke tildeler Kommissionen nogen skønsmargen, men udelukkende den tekniske opgave at fastslå, om der foreligger en væsentlig ændring i forholdene hvad angår eksisterende produktkategorier. Det er endvidere korrekt, at eventuelle relevante politiske beslutninger bør anses for at være foretaget af lovgiveren, navnlig at der for visse kategorier af eksisterende tobaksvarer var mulighed for en mindre restriktiv ordning.

3.20 Dette bekræftes af punkt 19 og 26, som Kommissionens begrundelse, der ledsager det delegerede direktiv, henviser til, og som siger følgende:

"(19) I betragtning af dette direktivs fokus på unge mennesker, andre tobaksvarer end cigaretter og rulletobak bør der gøres en undtagelse fra visse krav vedrørende indholdsstoffer, så længe der ikke sker væsentlige ændringer i forholdene hvad angår salgsvolumen eller forbrugsmønstre blandt unge mennesker."

"(26) For anden røgtobak end cigaretter og rulletobak, der hovedsageligt forbruges af ældre forbrugere og mindre dele af befolkningen, bør det være muligt fortsat at gøre en undtagelse fra visse mærkningskrav, så længe der ikke er væsentlige ændringer i forholdene hvad angår salgsvolumen eller forbrugsmønstre blandt unge mennesker. [...] For så vidt angår vandpibetobak, der ofte opfattes som mindre skadelig end traditionel røgtobak, bør den fulde mærkningsordning gælde for at undgå vildledning af forbrugerne."

3.21 Begrundelsen, der ledsager det delegerede direktiv og punkt 19 og 26, bekræfter, at de delegerede beføjelser vedrører lovgiverens politiske beslutning om at behandle visse kendte produktkategorier mindre strengt end andre. Ifølge Kommissionen blev cigaretter og rulletobak betragtet som attraktive for unge mennesker, og vandpibetobak blev anset for at kræve særbehandling på grund af påståede, fejlagtige opfattelser af dens skadelige virkning. De resterende kategorier blev betragtet som "*hovedsageligt indtaget af ældre forbrugere og små dele af befolkningen."* I betragtning af listen *over "særlige produktkategorier*" i artikel 2, stk. 14, litra a), og det faktum, at tobak, der indtages oralt, er forbudt i alle medlemsstaterne med undtagelse af Sverige, er det klart, at lovgiveren havde følgende for øje: pibetobak, cigarer, cigarilloer, tyggetobak og tobak, der indtages nasalt.

3.22 Lovgiveren indarbejdede derefter en sikkerhedsmekanisme, i fald der skulle ske en ændring i efterspørgslen fra cigaretter og rulletobak til en af disse produktkategorier (dvs. pibetobak, cigarer, cigarilloer, tyggetobak eller tobak, der indtages nasalt). En sådan delegeret beføjelse er faktisk af en rent "*teknisk*" karakter, nemlig at fastslå, om der var sket en "*væsentlig ændring i forholdene*" hvad angår en af disse kategorier. I så fald måtte Kommissionen fjerne undtagelsen for den pågældende kategori.

3.23 Uanset hvordan sagen analyses, ligger det uden for den "*tekniske opgave*" med at anvende prøven på væsentlig ændring i forhold, når der oprettes en ny produktkategori, som lovgiveren aldrig har taget i betragtning, og kategorien derefter pålægges de strengeste regler på trods af den nedsatte risikoprofil i forhold til cigaretter – og det er netop hvad det delegerede direktiv gør. Det indebærer også en betragtelig skønsmargen, og at der træffes valg ift. sundhedspolitikken. Ifølge Kommissionens egen indrømmelse overskrider det vedtagne delegerede direktiv derfor de delegerede beføjelser.

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11 Begrundelse, der ledsager det delegerede direktiv, afsnit 2.

3.24 **Det delegerede direktiv indfører ulovligt en ny "bestemt produktkategori" og krænker dermed også de generelle EU-lovprincipper om retssikkerhed og legitime forventninger**

3.25 Selv om det principelt var muligt for Kommissionen at regulere et nyt produkt med en delegeret beføjelse (hvilket det ikke er), overskrider det delegerede direktiv i væsentlig grad den beføjelse, der er delegeret til Kommissionen i medfør af artikel 7, stk. 12, og artikel 11, stk. 6.

3.26 Det delegerede direktiv introducerer den nye kategori "*opvarmede tobaksvarer*" i tobaksvaredirektivet. Artikel 7, stk. 12 og artikel 11, stk. 6 i tobaksvaredirektivet giver dog kun Kommissionen mulighed for at fjerne en undtagelse for eksisterende, veletablerede produktkategorier. De giver ikke Kommissionen mulighed for at oprette en ny "*bestemt produktkategori*".

Denne fortolkning understøttes af Kommissionens rapport, der blev vedtaget den 20. maj 2021.[12]

3.27 I denne rapport giver Kommissionen udtryk for, at definitionerne i tobaksvaredirektivet[13] bør ændres og forbedres, og at tobaksvaredirektivet ikke giver "*fleksibilitet til at definere nye produktkategorier.*"[14] Som forklaret i afsnit [3.8] herover, blev samme opfattelse gentaget af flere medlemsstater under processen med at indføre det delegerede direktiv, herunder i de fire medlemslandes fælles erklæring, hvori der stod: "*ved at introducere en definition af "opvarmede tobaksvarer" (...) overskrider Kommissionen ifølge os grænserne for de delegeringskompetencer, den er tildelt*".[15]

3.28 Desuden ville det være ulogisk, hvis Kommissionen nu kunne oprette nye produktkategorier, som den *retroaktivt* kunne anvende historiske data på for at fastslå en "*væsentlig ændring i forholdene*". Uanset hvad, hvis oprettelsen af en ny produktkategori skulle være mulig, ville den retroaktive anvendelse af prøven i sig selv være et separat grundlag for ugyldigheden af det delegerede direktiv, da dette ville være i strid med principperne om juridisk sikkerhed og legitime forventninger. Der er intet i tobaksvaredirektivets tekst eller dets lovgivningsmæssige historik, der antyder, at Kommissionen kan påberåbe sig artikel 7, stk. 12, og artikel 11, stk. 6 for at ændre reglerne for en ny kategori af tobaksvarer og underminere de investeringsbeslutninger, der træffes i henhold til disse regler. Den retsusikkerhed, der forårsages af det delegerede direktiv, blev sågar fremhævet af medlemsstaterne i deres fælles erklæring som nævnt i afsnit [3.8] ovenfor.

3.29 Den retroaktive anvendelse af prøven ville også give Kommissionen mulighed for at tage højde for de historiske data i forbindelse med tilpasning af definitionen af en ny produktkategori med henblik på at opfylde kriterierne i prøven på en "*væsentlig ændring i forholdene*". Sagt på en anden måde kan Kommissionen ved at definere en ny produktkategori på bredere eller smallere vis – set i lyset af historiske data – indirekte kontrollere, om der er sket en væsentlig ændring i forholdene. Faktisk synes Kommissionen at have gjort netop dette i nærværende tilfælde ved at oprette en ny produktkategori, der omfatter både produkter til rygning og røgfri produkter. Dette har gjort det muligt for Kommissionen at skabe og regulere en ny produkttype, nemlig opvarmede tobaksvarer til rygning, som, så vidt BAT ved, ikke findes på EU-markedet og bestemt ikke i mængder, der

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12 Rapport fra Kommissionen til Europa-Parlamentet, Rådet, Det Europæiske Økonomiske og Sociale Udvalg og Regionsudvalget om anvendelsen af direktiv 2014/40/EU om fremstilling, præsentation og salg af tobak og relaterede produkter, COM(2021) 249 endelig udgave af 20.5.2021 ("**Artikel 28-rapport**") findes her: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021DC0249&from=EN

13 Artikel 28-rapport, fodnote 43.

14 Artikel 28-rapport, side 12. Se også *bl.a.* med hensyn til opvarmede tobaksvarer erklæringen om, at tobaksvaredirektivet "*ikke (...) giver fleksibilitet til at håndtere hurtige produktudviklinger*". (side 12).

15 18. møde i gruppen af eksperter i tobakspolitik den 9. februar 2022

ville kunne betegnes som en "*væsentlig ændring i forholdene*". Dette kan ikke være en korrekt anvendelse af artikel 7, stk. 12, og artikel 11, stk. 6.

3.30 **Det delegerede direktiv indfører på ulovlig vis en ny "bestemt produktkategori", der ikke er i overensstemmelse med systemet i tobaksvaredirektivet**

3.31 Den nye kategori af opvarmede tobaksvarer, der introduceres i det delegerede direktiv, er også uforenelig med tobaksvaredirektivets system af to årsager.

3.32 For det første harmonerer det ikke, at den nye kategori af opvarmede tobaksvarer både er en ny kategori af tobaksvarer og en "*bestemt produktkategori*" på én og samme tid. Ifølge betragtning 4 og artikel 1 i det delegerede direktiv er en "*opvarmet tobaksvare*" en "*ny kategori af tobaksvarer*", som derfor ligger inden for rammerne af den generelle kategori "ny kategori af tobaksvarer" i henhold til betydningen i artikel 2, stk. 14 i tobaksvaredirektivet. Men som omtalt ovenfor i afsnit [3.12] er "*bestemt produktkategori*" og ny kategori af tobaksvarer to grupper, der udelukker hinanden. Derfor kan et produkt aldrig indgå i begge grupper. Det delegerede direktiv udvisker derfor de forskelle, som lovgiver har fastlagt mellem disse begreber og produktgrupper, ved uretmæssigt at behandle en ny kategori af tobaksvarer som en etableret produktkategori.

3.33 For det andet omfatter den nye kategori "opvarmede tobaksvarer", som defineret i det delegerede direktiv, både tobaksvarer, der er "*røgfri*", og "*røgtobak*". I tobaksvaredirektivet skelnes der dog klart mellem røgfri tobaksvarer og røgtobak,[16] og der opstilles meget anderledes og mere vægtige mærknings- og emballageregler for sidstnævnte,[17] hvilket afspejler deres grundlæggende forskelligartede karakter. Tobaksvaredirektivet indeholder endvidere udtrykkeligt bestemmelser om, at nye kategorier af tobaksvarer er omfattet af den ene eller den anden kategori, og i artikel 19, stk. 4, forklares det, at: "*Hvilke af bestemmelserne i dette direktiv, der finder anvendelse på nye kategorier af tobaksvarer, afhænger af, om de pågældende produkter falder ind under definitionen af en røgfri tobaksvare eller af røgtobak*", og forskellen mellem dem er dermed baseret på eksistensen af "*forbrænding*" eller den manglende eksistens deraf,[18] dvs. afbrænding af tobak og den deraf følgende frembringelse af røg.

3.34 Ifølge tobaksvaredirektivet er det derfor ikke juridisk muligt for en enkelt produktkategori at omfatte både røgfri tobaksvarer og røgtobak i forbindelse med tobaksvaredirektivet.

3.35 Af ovennævnte årsager udgør det delegerede direktivs indførelse af den nye kategori THP'er en væsentlig overtrædelse af tobaksvaredirektivet, hvilket, i medfør af artikel 290 i TEUF, naturligvis ikke er en beføjelse, der kunne være blevet delegeret til Kommissionen.

3.36 **Kommissionens tilgang til vurderingen af eksistensen af en "væsentlig ændring i forholdene" går ud over omfanget af den opgave, som den er blevet tillagt**

3.37 Som beskrevet ovenfor undersøges det i Kommissionens rapport, hvorvidt der er sket en "*væsentlig ændring i forholdene*" i henhold til betydningen i artikel 2, stk. 28, i tobaksvaredirektivet, og der konkluderes, at den første alternative betingelse og den nødvendige betingelse begge var opfyldt.

3.38 Med hensyn til undersøgelsen af den nødvendige betingelse, dvs. at salgsvolumen af den relevante produktkategori i detailleddet overstiger 2,5 % af det samlede salg af tobaksvarer

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16 Se definitionerne fra artikel 2, stk. 9, i tobaksvaredirektivet, der definerer røgtobak og røgfri tobaksvarer i afsnit [4.6-4.7] nedenfor.

17 De specifikke regler for røgtobak er fastlagt i artikel 9-11 i tobaksvaredirektivet, hvorimod de specifikke regler for røgfri tobaksvarer er fastlagt i artikel 12 i tobaksvaredirektivet.

18 Se definitionerne af "røgfri tobaksvarer" og "røgtobak" fra artikel 2, stk. 5, og artikel 2, stk. 9, i tobaksvaredirektivet i afsnit [4.6-4.7], som afhænger af, om der er tale om en "forbrændingsproces". Se også definitionen af "urtebaseret rygeprodukt" i artikel 2, stk. 15, i tobaksvaredirektivet, hvor der ligeledes henvises til, hvorvidt der foregår en "forbrændingsproces".

på EU-plan, søges det i Kommissionens rapport på upassende vis at vurdere dette på grundlag af "cigaretter". I den forbindelse udføres der i Kommissionens rapport en række komplekse datajusteringer og beregninger. Dette omfatter navnlig:

3.38.1 Der foretages justeringer af dataene for rulletobak, pibetobak og tyggetobak med henblik på at konvertere dataene for disse produktkategorier til "cigaret"-ækvivalenter for at kunne sammenligne dem med de andre produktkategorier.

(A) Rulletobak konverteres til "*cigaretter*" baseret på den antagelse, at 0,7 gram af produktet er lig med én cigaret.[19]

(B) Pibe- og tyggetobak konverteres til "cigaretter" ved at tage markedsandel af denne produktkategoris detailværdi og anvende denne på den samlede markedsstørrelse i "cigaretter".[20]

3.38.2 Data fra tre forskellige kilder (herunder en med ikke-officielle kommercielle data)[21] kombineres på forskellige måder, hvilket resulterer i, at salgsvolumen af opvarmede tobaksvarer skulle udgøre 3,33 % af alle tobaksvarers samlede salgsvolumen i EU i 2020.[22]

3.39 Ved at udvikle denne fejlbehæftede og komplekse metodologi og basere sine overvejelser derpå går Kommissionen ud over omfanget af den opgave, som den er tillagt i henhold til artikel 7, stk. 12, og artikel 11, stk. 6, i tobaksvaredirektivet, og som, som Kommissionen selv forklarer i den begrundelse, der ledsager det delegerede direktiv, "[ikke giver] Kommissionen noget skøn, men lader det være en teknisk opgave at fastslå, om der er sket en væsentlig ændring i forholdene for en bestemt produktkategori".[23] Det, som Kommissionen rent faktisk har gjort, rækker langt ud over en teknisk beregning, der ikke indebærer skøn (som den burde have været). Kommissionen har udviklet en kompleks metodologi, der indebærer forkerte valg, der tilsyneladende fører til det ønskede resultat, nemlig en overskridelse af grænseværdien på 2,5 %.

3.40 Grundlæggende set er Kommissionens tilgang til undersøgelsen af de forskellige produktkategorier udelukkende baseret på "*cigaretter*" tydeligvis upassende, da dette er et uanvendeligt grundlag for sammenligning af de forskellige produktkategorier. Eksempelvis er det ganske enkelt ikke korrekt at sige, at en cigaret plus en cigar er lig med "*to cigaretter*"; en cigar indeholder tydeligvis langt mere tobak end en cigaret. Ligeledes og helt grundlæggende set indeholder en cigaret meget mere tobak end en THP, dvs. cirka dobbelt så meget.

3.41 Tobaksmængden eller -vægten er selvfølgelig det korrekte kriterium med hensyn til markedsandelen, da hele formålet med aromaforbuddene i artikel 7, stk. 1, og artikel 7, stk. 7, i tobaksvaredirektivet og dermed det delegerede direktiv (som fjerner undtagelsen fra disse forbud for THP'er) er at reducere tobaksforbruget.[24] Som sådan svarer Kommissionens beslutning om at anvende en beregning baseret på en "*cigaret*" uden at tage højde for krystalklare forskelle mellem produkterne med hensyn til den tobaksmængde, som hvert produkt indeholder, til at sammenligne to vidt forskellige ting.

3.42 En beregning baseret på tobaksmængden eller -vægten er derfor den korrekte metode. En sådan metode ville også have undgået behovet for at bruge flere datasæt og komplekse beregninger, der indebærer betydelige og problematiske justeringer. Nøjagtige vægtbaserede

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19 Kommissionens rapport, tabel 3 asterisk og fodnote 3.
20 Kommissionens rapport, tabel 3 dobbelt asterisk og tabel 5 asterisk.
21 Dataene er hentet fra følgende tre kilder: (i) EU-CEG-data og Euromonitor-data om salg af opvarmede tobaksvarer i EU (Kommissionens rapport, tabel 2), (ii) Euromonitor-data om samlet salg af tobaksvarer i EU delt op efter produktkategorier (Kommissionens rapport, tabel 3) og (iii) Sporbarhedsproduktionstal for cigaretter og rulletobak, både tidsjusterede og ikke-tidsjusterede tal (Kommissionens rapport, tabel 4).
22 Kommissionens rapport, afsnit 2.2.3.
23 Begrundelse, der ledsager det delegerede direktiv, afsnit 2.
24 Tobaksvaredirektivet, betragtning 16.

data om alle produktkategorier ville også have været let tilgængelige for Kommissionen i form af EU-CEG-data.[25] I Kommissionens rapport nævnes der imidlertid intet om den vægtbaserede metode, og der angives ikke engang, at en opvarmet tobakspind kun indeholder omtrent halvdelen af den tobak, der er i en cigaret. Da cigaretter udgør langt størstedelen af tobaksmarkedet[26], hvilket er et spørgsmål om simpel og ligetil matematik, indebærer dette, at THP'ers markedsandel målt efter vægt vil være omtrent halvdelen af markedsandelen målt efter "cigaret"-princippet, dvs. omkring 1,65 % i stedet for 3,33 %, og dermed et godt stykke under grænseværdien på 2,5 %.

3.43 Ved ikke på behørig vis at undersøge og drage konklusioner ud fra de let tilgængelige data på passende faglig vis (og i stedet for foretage uberettigede metodiske valg for at nå frem til det resultat, den ønskede at opnå), er Kommissionen ulovligt gået ud over omfanget af den tillagte opgave og har i bund og grund manipuleret betingelserne for sin brug af de delegerede beføjelser.

3.44 Derudover har Kommissionen ikke givet offentligheden adgang til de underliggende data, hverken da det delegerede direktiv blev offentliggjort, eller efterfølgende efter anmodning. Dette har gjort det umuligt at foretage en rigtig undersøgelse af Kommissionens beregninger. BATs juridiske repræsentanter har anmodet om adgang til disse data samt vægtdata fra EU-CEG i henhold til forordning (EF) nr. 1049/2001. Imidlertid har Kommissionen afvist disse anmodninger[27] på baggrund af fuldstændigt usande påskud, herunder at Kommissionen ikke "ejede" dataene, og at de derfor tilsyneladende ikke kunne udleveres, og at tilvejebringelse af dataene af en eller anden grund ville omfatte "oprettelse af et nyt dokument", selv om dataene allerede var blevet anvendt af Kommissionen selv i forbindelse med dens beregninger.

3.45 Endelig bemærker vi, at Kommissionens rapport også indeholder en alternativ beregning baseret på Euromonitor-data om det samlede salg af tobaksvarer i EU efter værdi, opdelt efter produktkategorier, og den lander tilsyneladende på 3,51 %.[28] Der skal under alle omstændigheder ses bort fra denne beregning, da en sådan tilgang strider mod selve artikel 2, stk. 28, i tobaksvaredirektivet, hvori det fastlægges, at beregningen skal foretages på baggrund af "*salgsvolumen*", ikke "*salgsværdi*". Derfor vil ethvert forsøg på at retfærdiggøre det delegerede direktiv med henvisning til denne beregning være i strid med de tildelte uddelegerede beføjelser.

3.46 **Det delegerede direktiv er ugyldigt og bør ikke omsættes til dansk national ret**

3.47 Som det tydeligt fremgår af ovenstående, udgør det delegerede direktiv en ulovlig udøvelse af Kommissionens delegerede beføjelser. Det delegerede direktiv er derfor ugyldigt i henhold til EU-retten, og eventuel lovgivning om omsætning af det delegerede direktiv til dansk national ret vil også være ugyldig.

3.48 Som anført i afsnit [1.10] ovenfor anfægtes gyldigheden af det delegerede direktiv derudover i øjeblikket både for EU-Domstolen og for de irske domstole. Selv om Sundhedsministeriet mener, at det skal implementere det delegerede direktiv uanset ovenstående argumenter, bør der under disse omstændigheder anvendes en forsigtig tilgang, og gennemførelse bør ikke hastes igennem. Vi bemærker, at medlemsstaterne har indtil den 23. juli 2023 til at omsætte det delegerede direktiv til national lovgivning. Vi opfordrer Sundhedsministeriet til at vente til

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25 Blandt de oplysninger, der skal oplyses i EU-CEG-systemet, er den "[samlede] vægt af indholdet af tobak i én produktenhed i mg" (en produktenhed er en pind eller 1 g for løs tobak) (se Kommissionens gennemførelsesafgørelse (EU) 2015/2186, bilag, afsnit 3).

26 Kommissionens rapport, tabel 5.

27 BATs juridiske repræsentanter har indsendt en ansøgning om annullering af Kommissionens afgørelse om afslag, som i øjeblikket er under behandling for Retten (ansøgning indgivet den 12. september 2022, Herbert Smith Freehills v Kommissionen, T-570/22).

28 Kommissionens rapport, afsnit 2.2.4.

sidste øjeblik med at gennemføre direktivet, således at der muligvis først kan blive afsagt en EU-dom om det delegerede direktivs gyldighed forud for omsætningen.

4. DEFINITION OG KLASSIFICERING AF THP

4.1 Som nævnt ovenfor mener vi ikke, at Sundhedsministeriet på nuværende tidspunkt bør omsætte det delegerede direktiv til dansk ret. Hvis Sundhedsministeriet går videre med omsætningen, mener vi dog, at det foreslåede sprog i lovforslaget er egnet til at definere THP'er.

4.2 Det delegerede direktiv indsætter følgende i artikel 7, stk. 12, i tobaksvaredirektivet:

"*I første afsnit forstås ved »opvarmet tobaksvare« en ny kategori af tobaksvarer, der opvarmes for at frembringe en emission indeholdende nikotin og andre kemikalier, som derefter inhaleres af brugeren/brugerne, og som afhængigt af deres karakteristika er røgfri tobaksvarer eller røgtobak*." (det understregede er blevet tilføjet).

4.3 Ifølge det delegerede direktiv findes der to typer THP'er: røgfri og røgtobak, og klassificeringen af varen som røgfri eller røgtobak afhænger af varens egenskaber.

4.4 Lovforslaget gør på behørig vis noget ud af denne skelnen mellem røgfri tobaksvarer og røgtobak, og det foreslås at indsætte følgende definition i tobaksvarelovens § 2, stk. 31:

"Opvarmet tobaksvare: En ny kategori af tobaksvarer, der opvarmes for at frembringe en emission indeholdende nikotin og andre kemikalier, som derefter inhaleres af brugeren/brugerne, og som afhængigt af deres karakteristika er røgfri tobaksvarer eller røgtobak."

4.5 I lovforslaget anerkendes det endvidere, at det delegerede direktiv ved ændring af artikel 11, stk. 1, i tobaksvaredirektivet, alene fjerner muligheden for, at THP'er kan undtages fra kravet om påklæbning af den informationsmeddelelse, der er indeholdt i artikel 9, stk. 2, i tobaksvaredirektivet og den kombinerede sundhedsadvarsel fra artikel 10 i tobaksvaredirektivet: "*for så vidt de er røgtobak*".

4.6 I artikel 2, stk. 5, i tobaksvaredirektivet defineres røgfri tobaksvarer som "*en tobaksvare, der ikke forbruges via en forbrændingsproces, herunder tyggetobak, tobak, der indtages nasalt, og tobak, der indtages oralt*" (understregning tilføjet).

4.7 I artikel 2, stk. 9, i tobaksvaredirektivet defineres røgtobak som "*tobaksvarer, som ikke er røgfrie tobaksvarer*".

4.8 Den væsentligste forskel mellem røgfri tobaksvarer og røgtobak er altså tilstedeværelsen eller fraværet af en "*forbrændingsproces*". Med andre ord er de relevante produktkarakteristika ved klassificeringen som røgfri eller røgtobak, uanset hvordan produktet anvendes, hvorvidt det indebærer forbrænding eller ej.

4.9 Denne konklusion underbygges af en afgørelse fra forvaltningsretten i Stockholm, som afgjorde, at det eneste kriterium for vurdering af, hvorvidt et THP er "røgtobak" eller et "røgfrit tobaksprodukt", er, om der foregår forbrænding.[29]

4.10 Brugen af BATs THP, glo™, indebærer ikke en forbrændingsproces. Tobakken i disse produkter opvarmes (den forbrændes ikke), og der produceres en nikotinholdig aerosol, der generelt indeholder langt færre og lavere niveauer af giftige stoffer end almindelig cigaretrøg. For eksempel opvarmer glo™ tobakken. Når cigaretter ryges, antændes tobakken, hvilket resulterer i en eksotermisk proces, der fører til meget højere temperaturer samt kontinuerlig forbrænding og ulmen.

4.11 Konklusionen om, at BATs THP er røgfri, underbygges af retslige kendelser. Forvaltningsretten i Braunschweig (Tyskland) har f.eks. konkluderet, at THP'er er røgfri, fordi

[29] Forvaltningsdomstolen i Stockholm, sag nr. 3803-22, Philip Morris Products SA v The Public Health Authority, 26. september 2022.

de ikke indebærer en forbrændingsproces.[30] Den tyske føderale tilsynsmyndighed appellerede ikke denne kendelse, der nu er blevet inappellabel.

4.12 Den tyske domstol kom frem til denne konklusion efter at have overvejet ekspertudtalelsen fra Mitchell Smooke, en internationalt anerkendt ekspert i forbrændingsteori og lektor ved Yale University School of Engineering and Applied Science. En kopi af Mitchell Smookes råd findes i appendix (1).

4.13 Mitchell Smooke forklarede i sin analyse over for retten, at tobak kun antændes ved temperaturer på mellem 435 °C og 455 °C, hvilket er langt over driftstemperaturerne for THP-enheder, og at der uden forbrænding ikke kan være nogen "forbrændingsproces". Mitchell Smooke forklarede yderligere retten, at en opvarmet tobaksvareenhed opererer i en såkaldt "*før-antændingszone*", hvor temperaturerne ikke er tilstrækkelige til hverken antændelse eller forbrænding, og at THP-enheder derfor ikke genererer røg. Mitchell Smooke præciserede over for retten, at materialer, der opvarmes til en "*før-antændingszone*" og ikke yderligere, ikke undergår "*forbrænding*" eller en "*forbrændingsproces*".

4.14 Dette er i overensstemmelse med den amerikanske fødevare- og lægemiddeladministrations ("**FDA**") entydige konklusion om, at THP'er ikke indebærer en forbrændingsproces. I sin seneste godkendelse af markedsføring og salg af en THP på det amerikanske marked (omtalt nærmere nedenfor) omtalte FDA THP-enheden og relaterede forbrugsvarer som faldende inden for underkategorien "ikke-forbrændt" produkt. I beskrivelsen af THP-forbrugsvarerne angav FDA, at de er designet til at blive opvarmet elektrisk med henblik på at frigive nikotinholdige aerosoler og ikke er beregnet til at blive forbrændt. I sin beskrivelse af THP-enheden bemærkede FDA, at den elektroniske styring har til formål at opretholde et bestemt temperaturinterval, der gør det muligt at generere aerosoler og forhindrer, at den når temperaturer, hvor der kan forekomme forbrænding.[31]

4.15 Da BATs glo-THP'er er røgfri tobaksvarer, vil ethvert krav om at påklæbe informationsmeddelelsen fra artikel 9, stk. 2, i tobaksvaredirektivet og de kombinerede sundhedsadvarsler fra artikel 10 i tobaksvaredirektivet på glo-THP'er være ugyldigt.

4.16 Da der ikke foregår forbrænding, er den reducerede risikoprofil for opvarmede tobaksvarer sammenlignet med brændbare cigaretter blevet anerkendt af en række offentlige sundhedsorganisationer. Public Health England har eksempelvis konkluderet, "*at de foreliggende beviser tyder på, at opvarmede tobaksvarer kan være betydeligt mindre skadelige end tobakscigaretter.*"[32]

4.17 På samme måde fandt undersøgelser udført af UK Committee on Toxicology, "*at eksponeringen for problematiske forbindelser ved brug af ikke-forbrændte, opvarmede tobaksvarer er reduceret i forhold til eksponeringen fra almindelig cigaretrøg, og at det er sandsynligt, at den samlede sundhedsrisiko reduceres for konventionelle rygere, der skifter til ikke-forbrændte, opvarmede tobaksvarer.*"[33]

4.18 Senest har det hollandske institut for sundhed og miljø (RIVM) bemærket følgende: "*Overordnet set synes det at være en begrundet konklusion, at forbrug af THP'er i stedet for*

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30 Forvaltningsretten i Braunschweig, 4. kammer, sag nr. 4-A-427/20, British American Tobacco (Tyskland) GmbH v Forbundsrepublikken Tyskland, repræsenteret af det føderale kontor for forbrugerbeskyttelse og fødevaresikkerhed, den 23. september 2021.

31 Den amerikanske fødevare- og lægemiddeladministration, teknisk projektgennemgang af PMTA, s. 15, den 29. april 2019, tilgængelig på https://www.fda.gov/media/124247/download.

32 McNeill A, Brose LS, Calder R, Bauld L & Robson D., Evidence review of e-cigarettes and heated tobacco products 2018, A report commissioned by Public Health England, tilgængelig her, s. 220.

33 UK Committee on Toxicology, Toxicological Evaluation of novel heat-not-burn tobacco products – non-technical summary, 2017, tilgængelig her, s. 4.

cigaretter vil være forbundet med en væsentlig stigning i den forventede levetid for den undergruppe af rygere, der dør af kræft."[34]

4.19 Disse resultater understøttes af BATs forskning med peer-review, der viser, at niveauet af giftige stoffer i emissioner fra BATs glo-THP reduceres betydeligt på tværs af adskillige kemiske klasser i forhold til sammenlignelige brændbare cigaretter.[35] Nylig klinisk forskning med peer-review fra BAT har også udpeget væsentlige gunstige ændringer i biomarkører for potentiel skade over seks måneder og et år, hvor rygere skifter over til udelukkende at bruge BATs glo-THP, i forhold til fortsat at ryge cigaretter.[36] Forskningen viser, at mange af de gunstige ændringer i biomarkører for potentiel skade var af samme størrelsesorden som hos de deltagere, der ved forsøgets start var holdt op med at ryge uden at begynde at bruge en opvarmet tobaksvare. Denne forskning bidrager til dokumentationen af, at rygere, der skifter over til opvarmede tobaksvarer, derfor kan reducere deres relative sundhedsrisici i forhold til at fortsætte med at ryge.

4.20 Desuden viser de tilgængelige beviser, at der ikke er sket nogen betydelig stigning i unge, der begynder at bruge THP'er, og dermed ingen dokumenteret grund til bekymring over, at THP'er kunne fungere som gateway til øget brug af brændbar tobak eller øget påbegyndelse af rygning.[37] Dette underbygges af Kommissionens egen rapport, der som beskrevet ovenfor fandt, at der ikke var sket nogen væsentlig stigning i udbredelsen af brugen af disse produkter i gruppen af forbrugere under 25 år i Europa, og at den anden alternative betingelse for at påvise en "*væsentlig ændring i forholdene*" dermed ikke er opfyldt.[38]

4.21 Markedsføringen af THP'er er derfor i overensstemmelse med princippet om at reducere skader som følge af tobaksrygning, som er nedfældet i artikel 1, litra d), i WHO-rammeaftalen om tobakskontrol, da det eliminerer eksponering for tobaksrøg for rygere, der skifter fuldstændigt over til THP'er. Det delegerede direktiv er dog i strid med dette princip, da det delegerede direktiv ved at forbyde THP'er, der angiver smagsstoffer eller indeholder smagsstoffer i deres komponenter, gør opvarmede tobaksvarer mindre acceptable over for eksisterende rygere og dermed afskrækker dem fra at skifte og viderefører mere skadelig rygning (se afsnit [5] nedenfor).

4.22 EU-lovgiveren har selv anerkendt dette med hensyn til elektroniske cigaretter (et andet nyt produkt med betydeligt potentiale for at reducere skader som følge af tobaksrygning) ved i betragtning 47 i tobaksvaredirektivet at anføre, at "*[d]et kunne være nyttigt for medlemsstaterne at overveje at tillade markedsføringen af produkter med aromaer*", og at "*[f]orbud mod sådanne produkter med aromaer vil skulle begrundes*".

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34 Slob W, Soeteman-Hernández LG, Bil W, Staal YCM, Stephens WE, Talhout R. A Method for Comparing the Impact on Carcinogenicity of Tobacco Products: A Case Study on Heated Tobacco Versus Cigarettes. Risk Anal. 2020 Jul;40(7):1355-1366, tilgængelig her, s. 1362.

35 Forster M, Fiebelkorn S, Yurteri C, Mariner D, Liu C, Wright C, McAdam K, Murphy J, Proctor C. Assessment of novel tobacco heating product THP1.0. Part 3: Comprehensive chemical characterisation of harmful and potentially harmful aerosol emissions. Regulatory Toxicology and Pharmacology. 2018 Mar;93:14-33, tilgængelig her.

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5. SUNDHEDSMÆSSIGE KONSEKVENSER VED IMPLEMENTERING AF DET DELEGEREDE DIREKTIV

5.1 Lovforslaget og implementeringen af det delegerede direktiv vil med større sandsynlighed underminere den offentlige sundhed end forbedre den.

5.2 Med hensyn til de foreslåede smagsbegrænsninger vil disse have en negativ indvirkning på voksne rygere og sandsynligvis medføre utilsigtede konsekvenser for den offentlige sundhed. BAT har bestilt en ekspertrapport fra Sally Satel, M.D., som blev indsendt som svar på Europa-Kommissionens høring vedrørende tobaksvaredirektivet/evaluering af tobaksreklamedirektivet (en kopi af Sally Satels rapport findes i Appendix [2]). Dr. Satel er læge med speciale i misbrugspsykiatri og fast lektor ved American Enterprise Institute. Hun har ekspertise inden for sundhedspolitik, misbrug og skadesreduktion. Dr. Satel beskriver sin holdning til ikke-brændbare dampprodukters rolle med hensyn til at reducere skader som følge af tobak. Hun adresserer mange misforståelser vedrørende sundhedsrisiciene ved og effektiviteten af ikke-brændbare dampprodukter som erstatning for rygning, herunder vigtigheden af smagsstoffer og potentielle utilsigtede konsekvenser, der ville kunne opstå som følge af et smagsforbud.

5.3 I sin rapport bemærker Sally Satel, at en begrænsning af det, der gør ikke-brændbare dampprodukter attraktive, ved at begrænse smagsstoffer vil påvirke voksne rygere, dvs. den gruppe, som disse produkter er rettet mod. Baseret på den videnskabelige litteratur finder sådanne rygere ikke-brændbare dampprodukter med smag mere acceptable end dem, der har tobakssmag. Hun mener, at en begrænsning af tilgængeligheden af ikke-brændbare dampprodukter med smag vil have en række utilsigtede konsekvenser, herunder at brugerne genoptager rygning eller vender sig mod det uregulerede sorte marked, hvis deres foretrukne smagsstoffer ikke længere er tilgængelige.[39]

5.4 Ved derudover at anvende regler på THP'er, der er møntet på brændbare tobaksvarer, formidles det vildledende budskab, at de risici, der er forbundet med THP'er, er de samme som dem, der er forbundet med forbrug af brændbare tobaksvarer. Dette ville afskrække rygere fra at skifte over til RRP'er (*reduced risk products*). Disse synspunkter underbygges af den anerkendte professor i jura, økonomi og ledelse, W. Kip Viscusi, ved Vanderbilt University Law School i Nashville, USA, som også er en anerkendt ekspert i risikoopfattelse, og hvordan de påvirker forbrugeradfærden. (En kopi af Viscusis rapport findes i appendix [3]).

5.5 Viscusi bemærker i sin rapport, at mange mennesker mener, at opvarmede tobaksvarer er lige så skadelige eller mere skadelige end cigaretter. Cigaretrygere, der ikke mener, at THP'er er mindre skadelige end cigaretter, "*er ifølge rapporten mindre tilbøjelige til at prøve disse produkter eller bruge dem for tiden*"[40], hvorimod "*en tro på, at opvarmede tobaksvarer... er mindre skadelige end cigaretter, har en positiv sammenhæng med brugen af disse produkter. De respondenter, der opfatter opvarmede tobaksvarer som mindre skadelige end cigaretter, er 15 % mere tilbøjelige til at bruge opvarmede tobaksprodukter...*"[41] Han konkluderer, "*at det er muligt, at den seneste lovgivningsmæssige indsats, der behandler disse alternative produkter på samme måde som brændbare tobaksvarer, kan have udbredt denne fejlagtige opfattelse vedrørende ikke-brændbar tobak og nikotinprodukter.*"[42] Som sådan er det påviseligt irrationelt at anvende foranstaltninger, der vil have den virkning, at de undergraver brugen af alternative tobaksvarer og nikotinprodukter med en reduceret risikoprofil for rygere, der ellers fortsat ville ryge, og dermed videreføre brugen af mere farlige brændbare tobaksprodukter og underminere deres potentiale for at reducere skader som følge af tobaksrygning.

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39 Satels rapport s. VI og 97.
40 Viscusis rapport s. 73.
41 Viscusis rapport s. 18.
42 Viscusis rapport s. 107.

6. ALDERSKONTROL VED KØB

6.1 BAT Danmark støtter initiativer der kan understøtte en bedre aldersverificering ved køb af røgfrie nikotin- eller tobaksprodukter. Ingen unge under 18 skal have et nikotinforbrug eller have adgang til at købe nikotin- eller tobaksprodukter, og en bedre ID-kontrol ved salg af varer der er underlagt aldersbegrænsning er et skridt i retning af at forhindre unge under 18 år adgang til nikotin- og tobaksprodukter.

6.2 BAT Danmark ser derfor positivt på forslaget, men efterlyser en konkret model for aldersverificering f.eks gennem krav om et system med to-faktorgodkendelse, og ønsker generelt en bedre håndhævelse af reglerne omkring aldersverificering. I den seneste RØG undersøgelse svarer 54,1% af respondenter mellem 15-17 årige at de køber deres røgfrie nikotinprodukter i supermarkeder, mens 50,3% svarer at de køber røgfrie nikotinprodukter i kiosker[43]. Dette er stærkt bekymrende, da det i mange tilfælde er op til den enkelte ekspedient at bede om og kontrollere ID, hvilket kan løses gennem krav om elektronisk system med tofaktorgodkendelse, hvor et køb af en aldersbegrænset vare, kun kan lad sig gøre, hvis kunden er over 18 år. Køb foretaget med kontantbetaling skal forudsætte aldersverificering, ved forevisning af gyldigt billedlegitimation.

6.3 På samme vis ønsker BAT at sidestille onlinehandel med handel i fysiske butikker, således at der opnåes en symmetri i reglerne. I dag er der ikke i tilstrækkelig høj grad alderskontrol ved onlinekøb af røgfrie nikotinprodukter, hvorfor det også her vil være oplagt at sikre en systematisk aldersverificering gennem et system med to-faktor-godkendelse inden købet kan gennemføres.

7. KONKLUSION

7.1 Af ovennævnte årsager er det delegerede direktiv ugyldigt ifølge EU-retten, da enhver lov der implementerer det Delegerede Direktiv i Dansk lov vil være ugyldig. Sundhedsministeriet bør derfor ikke omsætte det til dansk ret. Hvis Sundhedsministeriet alligevel fortsætter med gennemførelsen, bør det dog vente til sidste øjeblik med omsætningen, på baggrund af de igangværende retssager, og beholde den definition af THP, som er foreslået i det aktuelle lovforslag.

7.2 Vi opfordrer på det kraftigste Sundhedsministeriet til at overveje vores kommentarer til lovforslaget og arbejder gerne yderligere sammen med Sundhedsministeriet om dette.

[43] Brug af røgfrie nikotinprodukter blandt unge (sst.dk)

An Assessment of the Combustion Characteristics of Glo™

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1. Introduction

This report seeks to answer the following two questions:

1) During its intended operation, does Glo™ undergo the process of combustion?

and

2) Does the aerosol produced by Glo™ Neosticks constitute smoke?

To better understand the answers to these questions, this report focuses on a detailed discussion of the basic concepts of combustion that are necessary to explain my conclusions. These include chemistry, heat release, ignition, and the corresponding products of combustion with regard to the behavior of fuels such as gaseous and liquid hydrocarbons and organic materials such as tobacco.

2. Overview

Aside from powering our transportation system and generating electricity for our homes, combustion has been used in a variety of smaller systems such as gas appliances and small power tools to recreational uses in camping, cook-outs and in the consumption of tobacco products. The last of these topics forms the primary focus of this report.

There are a number of devices called *tobacco heating products* (THPs) that utilize tobacco materials in a cylindrical shaped stick that is an alternative to the consumption of cigarettes. The Glo™ device electronically heats cylindrical Neostick rods that contain tobacco and are specially designed to work only with the Glo™ device. THPs differ from cigarettes primarily in the mode of operation for nicotine delivery.

In this report a systematic discussion of the process of combustion is provided and an assessment of whether THPs and, in particular, British American Tobacco's product Glo™ undergo combustion. In the next section the importance of chemical reactions, ignition and heat release in the burning of hydrocarbon fuels is discussed. Section 4 considers the burning of tobacco and the operation of Glo™. The report concludes with an assessment of whether Glo™ undergoes the process of combustion and whether the aerosol produced by the Glo™ device is smoke. Reference material is provided in the appendices that puts in perspective the fundamental physical and chemical aspects of combustion.

3. Chemical Reactions, Ignition and Heat Release

Most combustion processes occur under what is termed forced ignition whereby a heat source is applied to a fuel-air mixture. Fuel-air mixtures include, for example, wood (fuel) burning in a fire place or gasoline (fuel) burning in an engine or tobacco (fuel) burning in a cigarette or pipe. Assuming that the mixture is within the flammability limits (see *Appendix H*), combustion follows a several step process.

As the system is heated, volatile gases begin to emerge from the fuel (pre-heat zone). As the temperature of the system continues to increase, the volatile materials in the fuel are vaporized (pre-ignition zone) which can be followed by a region of pyrolysis. As the temperature rises further and the ignition temperature of the fuel is reached, combustion begins. Depending upon the organic molecules being burned, organic nano-particles can be formed (soot) which are either oxidized in the flame or, in some cases, released into the atmosphere as smoke.

For the purposes of this report, it is worthwhile to distinguish between an aerosol that is composed of combustion (smoke) versus noncombustion products. From a combustion perspective, smoke refers to the gaseous products of the burning of organic materials in which small solid and liquid particles are dispersed [1]. Other definitions consider smoke to be the aerosol or condensed phase component of the products of combustion. While particulate formation can occur from pyrolysis, the temperature needs to be in the 325C-625C range [2]. An aerosol composed of noncombustion products (e.g., water vapor and other vaporized liquids) is not smoke. Thus, while all smoke is an aerosol, not all aerosols are smoke.

For any fuel-air system, it is essential to understand the temperature at which the pre-heat, pre-ignition and ignition stages are reached. Detailed studies of ignition temperatures for a variety of hydrocarbon fuels have been tabulated over the years and a sample is included in Figure 4 in *Appendix H* [3]. What is clear is that the temperature plays a critical role in the combustion of fuel-air systems. Irrespective of whether the fuel is a solid, a liquid or a gas, combustion will not occur until the temperature is above the ignition value.

4. Tobacco, Tobacco Heating Products and the Operation of Glo™

Tobacco is a plant from the Solanaceae family, better known as Nicotiana (genus). This family comprises some 2,000 species, including herbaceous plants, bushes, trees and vines. There are several varieties of tobacco [4] such as Brightleaf, Burley, Corojo, Dokha, Habano, Latakia, Perique, Shade, etc. Nicotiana tabacum, or common tobacco, is the primary source of tobacco in cigarette manufacturing.

Tobacco plants are composed of a variety of chemicals, including: nicotine, chlorophyll, water, sugars, a variety of minerals etc. For example, nicotine, a chemical naturally present in the tobacco plant, is composed of carbon, hydrogen and nitrogen atoms with the chemical formula $C_{10}H_{14}N_2$. Nicotine has a specific evaporation temperature within the range of the Glo™ device operating temperature [5].

The harvesting of tobacco occurs when it is ripe, i.e., when the leaves begin to turn yellow. The tobacco leaves are then dried which provides a means of rapidly destroying chlorophyll (the leaf goes

from green to brown), converting starch into sugars, and reducing the moisture that is naturally present in the leaves.

Of critical importance to the burning of tobacco is the ignition temperature. Studies that address the ignition temperature for tobacco date back to the early 1900s ([6] and [7]). Other studies were carried out in the 1940s ([8] and [9]). Most of these studies focused on leaf tobacco which required a large number of leaves to minimize the effects of tobacco leaf variability due to differing levels of moisture, fertilizer, chemical addition etc. To reduce such effects, several studies employing ground tobacco, which was formed into a pellet and subsequently burned, were undertaken by Weybrew [10] as well as by Elliot and Vickery [11]. Additional studies were carried out by McKee [12] and Tibbitts [13] in the late 1950s and early 1960s.

Specifically, in the results reported in [13], a 15 inch (in length) heating element with a uniform temperature gradient was used to determine the tobacco ignition temperature. The heating element consisted of a ceramic tube which was wound with Nichrome V wire. By adjusting spacing from one turn to the next, it was possible to generate a linear temperature gradient along the tube. Thermocouples were used to measure the temperature and the entire unit was enclosed to prevent convective effects from local air currents. The heating element temperature was regulated with a variable transformer. Ignition temperatures were determined by sifting tobacco onto the heating element. The sifting process started at the cooler end and continued across the element to the hottest region of the ceramic element.

The point at which the majority of the ground tobacco ignited was recorded as the ignition temperature of the sample [13]. Multiple tests were undertaken for each sample. The results of the study were fairly consistent in that the ignition temperatures of the sample ranged from 442C to 488C. The study confirmed earlier results by McKee [12] where ignition temperatures were determined to range between 435C and 455C. In spite of the age of these studies, the results are consistent with more recent investigations carried out in 2005 and 2007 ([14] and [15]). Thus, these studies reliably establish the ignition temperature of tobacco between 435C and 455C. Similarly, peer-reviewed published thermogravimetric analysis indicates that ignition of the tobacco rod in the Glo™ Neostick occurs at temperatures above 400C [16].

Factory made cigarettes are the main form of tobacco used globally. When smoked, the tobacco is combusted at temperatures that can exceed 800C. In addition to the heat released, cigarette burning produces smoke that can be composed of over 6500 identified chemicals [17] (see also [16] and [18]). A number of these constituents are thought to be toxicants [19]. Prolonged exposure to these chemicals over time can lead to a variety of health issues such as cardiovascular disease and cancer [20]. As in the case of hydrocarbon fuels, the primary products of tobacco combustion include H_2O, CO_2, CO and the oxides of nitrogen NO, NO_2 and, more generally, NO_x.

British American Tobacco's Glo™ is a smoke free THP that uses an electronic battery-powered device to heat specially designed tobacco sticks called Neosticks to produce an aerosol consisting of primarily nicotine, glycerin, flavorings and water (see Figure 1). BAT's Glo™ product differs from cigarettes in that the tobacco is heated to temperatures in the neighborhood of 242±5C with an electrical heating device. These temperatures are significantly lower than the 800C range of ordinary cigarettes.

Figure 1 – Illustration of the Glo™ Product. Reprinted with permission from British American Tobacco.

The Neostick contains the tobacco material and a filter. When heated, the user draws the aerosol from the Neostick. An electronic battery-powered heating element provides the heat source. When the Neostick is inserted into the heating element, the tobacco material is heated to approximately 242C and creates an aerosol that the user inhales.

The battery is a lithium-ion battery that can last for 30 sessions. A series of small holes at the bottom of the device allows air to be brought into the device. The device has a micro USB charging port and the heating device, Neostick and battery are contained within an aluminum sleeve which protects the device and helps to maintain the temperature so that the device remains cool to the touch.

As discussed above, when the temperature is below the ignition temperature of tobacco, combustion does not take place and smoke is not formed. For the Glo™ device, this manifests itself with only trace levels of toxicants such as CO, CO_2, NO and NO_x. Moreover, such low levels of toxicants in Glo™ aerosol emissions (relative to smoke from traditional cigarettes) similarly compels a conclusion that Glo™ emissions do not constitute tobacco smoke. In fact, the low levels of reported toxicants in Glo™ emissions result from heating processes occurring at temperatures well below the ignition temperature required for tobacco combustion and smoke production. The extremely reduced levels of such toxicants in the Glo™ aerosol as compared to cigarette smoke evidences the absence during Glo™ operation of both a combustion process and the smoke formation known to produce the high numbers and levels of toxicants in cigarette smoke.

5. Conclusion

The previous sections and the subsequent appendices discuss the complex interaction of fluid mechanics, heat transfer, radiation and chemistry in the process of combustion of hydrocarbon molecules. The burning of a fuel molecule undergoes a multistep procedure that includes a pre-

heat, pre-ignition, pyrolysis and ignition zone. For nonspontaneous combustion to take place, the fuel must be heated with an outside ignition source. Each hydrocarbon molecule has a unique temperature at which ignition occurs depending upon the pressure and flammability region. As noted above, tobacco ignition takes place at temperatures at or above 435C. Once the fuel is heated above the ignition temperature, a rapid rise in the temperature is observed and the primary products of combustion are produced.

If the temperature does not get above the ignition limit, combustion does not take place and the system operates in the pre-heat, pre-ignition or pyrolysis zone. Based upon the temperature and heating specifications of British American Tobacco's THP Glo™ and the fact that tobacco does not ignite at temperatures below approximately 435C, the Neosticks product does not undergo combustion.

Instead, Glo™ operates in a pre-ignition environment, i.e., in a temperature regime where the primary products of combustion, such as CO, CO_2, various hydrocarbon molecules and the oxides of nitrogen are significantly reduced to only trace levels. In addition, since a tobacco combustion process does not take place, the device does not produce an aerosol that can be classified as tobacco smoke.

Disclaimer: This report does not endorse nor discourage the use of tobacco heating products. The views expressed herein are those of the author.

Overview of the Appendices

Practical combustion systems are governed by large systems of strongly coupled, highly nonlinear partial differential equations (PDEs) and algebraic constraints that describe the conservation of total mass, momentum, and energy, and the evolution of individual species mass under the mechanisms of convection, molecular diffusion, and chemical reaction. In the Appendices that follow, the various submodels that are inherent to the mathematical modeling of combustion processes are discussed. The section ends with a discussion of flammability limits and ignition.

Appendix A

Governing Equations

It is possible to derive the governing equations from control volume considerations, as is often done in textbooks. A more rigorous derivation is also possible using the Boltzmann equation of kinetic theory, under the assumption that a continuum approximation is justifiable and departures from local thermodynamic equilibrium are small. This is the case whenever the molecular mean free path is much shorter than any other relevant length scales in the system, or equivalently, when the Knudsen number is much less than unity. Statistical mechanics reveals that the mean free path is directly proportional to temperature and inversely proportional to pressure, and that the Knudsen number is about 1.5 times the ratio of the Mach number to the Reynolds number. It follows that at terrestrial (or elevated) pressures and typical flame temperatures, there is no question about the validity of the classical continuum equations for modeling deflagrations. Since their derivation is presented in many other places (e.g., [21, 22]), they are reproduced here in vector form.

Conservation of total mass:

$$\frac{\partial \rho}{\partial t} + \nabla \cdot \rho \mathbf{u} = 0 \tag{1}$$

Conservation of momentum:

$$\frac{\partial \rho \mathbf{u}}{\partial t} + \nabla \cdot \rho \mathbf{u}\mathbf{u} = \nabla \cdot \mathbf{S} + \mathbf{f} \tag{2}$$

Conservation of energy:

$$\frac{\partial \rho e}{\partial t} + \nabla \cdot \rho \mathbf{u} e = \nabla \cdot (\mathbf{u} \cdot \mathbf{S}) - \nabla \cdot \mathbf{q} + \mathbf{u} \cdot \mathbf{f} + \mathbf{Q} \tag{3}$$

"Conservation" of individual species k:

$$\frac{\partial \rho Y_k}{\partial t} + \nabla \cdot \rho Y_k \mathbf{u} = -\nabla \cdot \mathbf{j}_k + \mathbf{R}_k \tag{4}$$

where here, as always, the species index k ranges over the N_{sp} members of the set of species in the chemistry model, $\mathcal{S}$. To this set of differential equations must be added the equation of state for an ideal gas, which relates the density to the other thermodynamic variables:

$$P = \rho \, R \, T \sum_{k \in \mathcal{S}} \frac{Y_k}{W_k} \ . \tag{5}$$

The unknowns in the governing equations are the "primitive variables": P, which denotes the total pressure; $\mathbf{u}$, fluid velocity vector; T, temperature; Y_k, mass fraction of species k; and ρ, density. The other quantities appearing in the equations are t, time; $\mathbf{S}$, stress tensor; $\mathbf{f} = \sum_{k \in \mathcal{S}} \mathbf{f}_k$, body force vector, where the force can in theory vary depending on the chemical species (e.g., due to electromagnetic fields in a plasma), though in this work it will simply be a constant force due to

gravity ($\mathbf{g}$); e, specific total energy (chemical, sensible, and kinetic); $\mathbf{q}$, diffusive energy flux vector; $\mathbf{Q}$, volumetric energy source (e.g., due to an ignition source or a laser), to be ignored in this work; $\mathbf{j}_k$, diffusive mass flux of species k; $\mathbf{R}_k$, volumetric mass production rate of species k due to chemical reaction; R, universal gas constant; and W_k, molecular mass of species k. The symbol ∇ is the vector derivative operator. Note that whereas the total mass of each different chemical *element* is conserved, strictly speaking, the mass of each of the species in $\mathcal{S}$ is not conserved.

A number of quantities in the governing equations must be defined in terms of the basic thermochemical and fluid dynamic variables, including the stress tensor and the other transport fluxes with their respective transport coefficients, as well as models for molecular diffusion, chemical reaction, and radiation. Experiments show that in a broad class of fluids, known as Newtonian, the stress-strain relation is approximately linear. For such fluids, the two components of the vector momentum conservation equation are known as the Navier-Stokes equations. The related transport fluxes are written in *Appendix B* with mass conservation constraints and diffusion models discussed in *Appendices C*, and *D*, respectively. The evaluation of thermodynamic properties and transport coefficients is a critical and often time-consuming part of detailed computations of reacting flows. The thermodynamic properties appearing in the governing equations are the species and mixture specific heats, the species enthalpies and, along with the required transport coefficients such as the dynamic viscosity, the thermal conductivity, and the mixture-averaged diffusion coefficients, are discussed in *Appendix E*. In fact, all of the transport coefficients are formed by a kind of averaging process given the relevant coefficients for each component in the mixture. This mixture-averaged approach to transport modeling has long been the *de facto* standard in combustion modeling due to its incorporation in various software packages.

Appendix B

Transport Fluxes

As discussed in Appendix A, the system of governing equations contains a number of quantities which must be defined in terms of the basic thermochemical and fluid dynamic variables. Specifically, the stress tensor has the following familiar form:

$$\mathbf{S} = -P\mathbf{I} + \mathbf{T} \tag{6}$$

$$\mathbf{T} = \mu\left((\nabla\mathbf{u}) + (\nabla\mathbf{u})^T\right) - \frac{2}{3}\,\mu\,\nabla\cdot\mathbf{u}\;\mathbf{I}\;, \tag{7}$$

i.e., the sum of the isotropic pressure tensor and the viscous stress tensor ($\mathbf{T}$). Here, μ is the dynamic viscosity of the mixture and $\mathbf{I}$ the unit tensor. As is common in the study of low speed flows of dilute gases, the bulk viscosity is assumed to be negligible. The dynamic viscosity is a function of the thermodynamic state of the mixture, like the other transport coefficients; The diffusive fluxes of energy and mass are given by the expressions:

$$\mathbf{q} = -\lambda\nabla T + \sum_{k\in\mathcal{S}} h_k\mathbf{j}_k + \mathbf{q}_{rad} \tag{8}$$

$$\mathbf{j}_k = \rho Y_k\mathbf{u}_k\;. \tag{9}$$

The diffusion velocities $\mathbf{u}_k$ will be discussed below. The terms in the energy flux relate to conduction (Fourier's Law, with λ the coefficient of thermal conductivity), the transport of enthalpy by molecular diffusion (h_k, specific enthalpy of species k), and the net effect of radiation ($\mathbf{q}_{rad}$). The divergence of the radiative flux will be treated separately from the other heat transfer phenomena. The Dufour effect, whereby an energy flux arises from concentration gradients, is typically negligible in high-heat-release combustion processes, and hence is omitted above.

One change of note concerns the energy equation, which is transformed into an equation for temperature using various thermodynamic relationships for energy and enthalpy. Its derivation is tedious and, since this is sketched elsewhere [23], it is simply quoted here:

$$\rho c_P\frac{DT}{Dt} = \omega_T' + \frac{DP}{Dt} + \nabla\cdot(\lambda\nabla T) - \left(\rho\sum_{k\in\mathcal{S}} c_{P,k}Y_k\mathbf{u}_k\right)\cdot\nabla T - \nabla\cdot\mathbf{q}_{rad} + \mathbf{T}{:}\nabla\mathbf{u}\;. \tag{10}$$

In this equation, c_P and $c_{P,k}$ are the specific heats at constant pressure of the mixture and species k, respectively; $\omega_T' = -\sum_{k\in\mathcal{S}} h_k W_k\dot{\omega}_k$, the heat source due to chemical reaction, with $\dot{\omega}_k$ the molar production rate of species k; and D/Dt denotes the material derivative. The term involving the viscous tensor describes the addition of heat due to viscous effects in the fluid ("friction"); both it and the material derivative of pressure, related to mechanical work, are negligible for low speed unconfined flows. The term arising from work due to body forces has been suppressed since it is identically zero for the case of a constant force affecting all species equally. This conclusion follows from the second of the mass conservation constraints that are presented below.

Appendix C

Mass Conservation Constraints

From the definitions of the mixture density and mass-averaged velocity in terms of the (partial) densities and flow velocities of the individual species, it follows that the N_{sp} mass fractions and the N_{sp} diffusion velocities are not a priori independent but satisfy the following constraints:

$$\sum_{k\in\mathcal{S}} Y_k = 1 \qquad \sum_{k\in\mathcal{S}} Y_k \mathbf{u}_k = 0 \ . \tag{11}$$

To these one can add another mass conservation constraint that derives from the chemical source terms:

$$\sum_{k\in\mathcal{S}} \mathbf{R}_k = \sum_{k\in\mathcal{S}} W_k \dot{\omega}_k = 0 \ . \tag{12}$$

These constraints give mathematical expression to the physical impossibility of a net creation of mass or a net diffusion of mass relative to the mass-averaged bulk flow. With them, it is easy to show that the total mass conservation equation results from summing up all the species equations. However, this proves yet again that the equation set is overdetermined, and raises questions about which equations to include in the model and how to enforce the governing equations and constraints simultaneously.

The first constraint on the sum of the mass fractions can be dealt with in two ways. For strongly diluted flames burning in air, it is possible to compute Y_{N_2} from the constraint and to omit the equation that governs its transport in the flow field. This "asymmetric" treatment of the mass fractions lumps all the errors into the mass fraction of the (inert) diluent. Clearly, this will not be satisfactory whenever these errors may be relatively large compared with its typical value, e.g., in oxyfuel flames [23, p. 16]. The more general (and perhaps more challenging) approach is to treat all mass fractions similarly by solving the complete set of species balance laws. In this case, the constraint cannot be imposed but must rather be "deduced from the governing equations" [24, p. 8].

The second mass conservation constraint requires that the species diffusion fluxes sum to zero at every point in the flow. The calculation of the diffusion velocities will be discussed shortly; for now, it is enough to assume that they are available. When computing highly diluted flames with approximate transport coefficients, a common and accepted approach is to "lump" all the diffusion velocity errors into the diffusion velocity of nitrogen, i.e., to take

$$\mathbf{u}_{N_2} = -\frac{1}{Y_{N_2}} \sum_{k\in\mathcal{S},k\neq N_2} Y_k \mathbf{u}_k \ , \tag{13}$$

which indeed satisfies the constraint. As with the "asymmetric" treatment of the mass fraction unknowns above, this approach could be problematic for flames where nitrogen is not present in excess. A more general way of ensuring this constraint is satisfied is to add a correction velocity to the diffusion velocity of each species at each point in the flow field. This is an established approach

that was introduced a generation ago [25, 26]. The correction velocity is defined as

$$\mathbf{u}^c = -\sum_{k\in\mathcal{S}} Y_k \mathbf{u}_k \ . \tag{14}$$

Note that the problem to which this correction velocity is a solution arises from the mutual incompatibility of the diffusion velocities as calculated from common *approximate* formulas; if the best known model for these velocities were used to compute them, they would automatically satisfy the constraint and the correction velocity would vanish.

Appendix D

Diffusion Model

The modeling of molecular diffusion in multicomponent gaseous mixtures is a very complicated subject in its own right. As commonly formulated, the problem is to compute the diffusion velocity $\mathbf{u}_k$ of each chemical species k at each point of the flow given the concentrations, concentration gradients, and other thermodynamic variables throughout the flow field. This requires the solution of linear systems of dimension N_{sp} at every point of the computational domain. These linear systems derive from the so-called multicomponent diffusion equations, which are a generalization of the Stefan-Maxwell equations for binary diffusion [21, App. E.2.1]:

$$\nabla X_k = \sum_{l \in \mathcal{S}} \frac{X_l X_k}{D_{lk}} \left(\mathbf{u}_l - \mathbf{u}_k \right) + \sum_{l \in \mathcal{S}} \left[\frac{X_l X_k}{\rho D_{lk}} \left(\frac{D_{T,l}}{Y_l} - \frac{D_{T,k}}{Y_k} \right) \right] \left(\frac{\nabla T}{T} \right) + \left(Y_k - X_k \right) \frac{\nabla P}{P} \ . \tag{15}$$

The first term relates mole fraction gradients to relative diffusion velocities; the second to thermophoresis, or the Soret effect, which unlike its "reciprocal," the Dufour effect, is not necessarily negligible in combustion; and the third to pressure gradients in the flow field, this being a differential effect only felt when the molecular weights of the species vary considerably from the average molecular weight of the mixture. Here it is assumed that the body forces $\mathbf{f}_k$ acting on each species are equal, or else yet another term would arise. The mole fractions X_k are related to the mass fractions by

$$X_k = \frac{Y_k}{W_k} \left(\sum_{l \in \mathcal{S}} \frac{Y_l}{W_l} \right)^{-1} \ , \tag{16}$$

where the quantity in parentheses is the inverse of the molecular weight of the mixture.

This typical formulation of the multicomponent diffusion model is generally applicable when the governing equations are integrated in time using an explicit method, i.e., when the state variables are considered to be known at the beginning of each time step; however, when a fully implicit solver is applied to a flame problem it is no longer strictly possible to fix these variables and solve for the diffusion velocities in this fashion [27, p. 15]. In this situation, the recommended approach is to use a different (and more esoteric) formalism in which the diffusion fluxes or, equivalently, the diffusion velocities are expressed as linear combinations of diffusion driving forces. Here, the diffusion matrix that defines these linear combinations is populated by coefficients which must themselves result from the solution of transport linear systems. The practical development of these multicomponent transport models is largely the work of Giovangigli and Ern [24, 28]. Thanks to their EGLIB software library, it is now possible to solve the full multicomponent diffusion problem much more efficiently than in the past [29].

This is not to say, however, that these fast transport algorithms are inexpensive, or a realistic option in typical flame calculations; in general, they still require the approximate iterative solution of a linear matrix equation for the diffusion matrix at every point in the domain and at every time step of a transient calculation. Moreover, the benefit of all this extra work is not always apparent. For the study of either very light or very heavy fuels where the Soret effect is expected to be significant,

it could be worthwhile and might, in some cases, be necessary for the accurate modeling of sensitive phenomena, such as thermo-diffusive instability [30–32]; but for a standard laminar hydrocarbon flame, a sophisticated multicomponent diffusion model is generally unnecessary. Instead, a highly simplified diffusion model can often be employed – Fick's law with the mixture-averaged diffusion coefficients:

$$Y_k \, \mathbf{u}_k = -D_{km} \nabla Y_k \ , \tag{17}$$

where D_{km} is an effective average diffusion coefficient of species k into the mixture. The calculation of these diffusion coefficients will be discussed below.

It needs to be clearly stated that this approximation is not the best simple diffusion model available. It can be shown that the Hirschfelder and Curtiss approximation with mixture-averaged diffusion coefficients, i.e.,

$$X_k \, \mathbf{u}_k = -D_{km} \nabla X_k \ , \tag{18}$$

leads, in conjunction with the correction velocity approach introduced in *Appendix C*, to the best first-order approximation to the solution of the Stefan-Maxwell equations [23, p. 14]. Admittedly, the difference here with the Fick's Law approximation appears to be slight. Nevertheless, the Fickian approach based on mass fractions is often simpler to implement since the Y_k are immediately available, whereas X_k must be computed from Equation (16). Note that the two approximations are equivalent if the spatial gradients of the molecular weight of the mixture vanish.

Appendix E

Thermodynamic Properties and Transport Coefficients

The evaluation of thermodynamic properties and transport coefficients is a critical and often time-consuming part of detailed computations of reacting flows. The thermodynamic properties appearing in the governing equations are the species and mixture specific heats and the species enthalpies. The required transport coefficients are the dynamic viscosity, the thermal conductivity, and the mixture-averaged diffusion coefficients. In fact, all of the transport coefficients are formed by a kind of averaging process given the relevant coefficients for each component in the mixture. This mixture-averaged approach to transport modeling has long been the de facto standard in combustion modeling due to its incorporation in the Chemkin software library; the utility of more complete models, such as those available in the EGLIB software package, is measured against this standard.

The original Chemkin software was written at Sandia and published in two separate packages in the early 1980s, one dealing with chemical kinetics and thermodynamics and the other with the calculation of transport properties [33, 34]. In some places, it has been customary to refer to the first package as "Chemkin" and the second as "Transport" (the latter name was not given by the authors of the software). A second-generation Chemkin, known as Chemkin-II, was disseminated a decade later, by which time an updated transport package had also been introduced [35, 36]. These two versions of Chemkin each have their own "interpreter" software for reading specially formatted chemical species and kinetic information. The versions are mutually incompatible. More recent versions also exist in the form of commercial software. All the early versions of Chemkin were written for scalar computers and hence were found to suffer suboptimal performance on the newer vector and parallel computers that were starting to be used in the late 1980s. This deficiency was addressed originally by Giovangigli and Darabiha, who extracted many critical subroutines in both Chemkin packages and vectorized them, leading to considerable speed-ups both in these routines and, to some extent, in the overall flame solver [37].

The evaluation of the energy equation in the temperature variable requires the three thermodynamic properties of the mixture mentioned above, as well as the mixture density, which is recovered from the ideal gas law (also through a Chemkin call). The specific heat capacity at constant pressure for the k^{th} species depends only on temperature. It is computed efficiently from polynomial fits based on data in the JANNAF Thermochemical Tables, as found, for example, in the database of the NASA chemical equilibrium code [38], which is also used by Chemkin. The mixture specific heat at constant pressure is then taken as the mass average of the species specific heats. The species specific enthalpies are given mathematically by a definite integral of the species specific heats over a prescribed temperature range; in Chemkin, however, these quantities are computed more efficiently as simple polynomial fits of the published data.

There is more than one way of defining mixture-averaged transport coefficients. For the thermal conductivity and the viscosity, semi-empirical formulas are available as well as more complicated expressions. An example of the latter is the formula for the mixture thermal conductivity due to Wilke, which involves a double summation and ratios of species properties raised to integer and non-integer powers (the equations can be found in many references, e.g., [37]). Because of the expense of calculating Wilke's formula, the mixture thermal conductivity is often computed from

the semi-empirical formula:

$$\lambda = \frac{1}{2}\left[\sum_{k\in\mathcal{S}} X_k\lambda_k + \left(\sum_{k\in\mathcal{S}} X_k\lambda_k\right)^{-1}\right] \ , \tag{19}$$

where the species thermal conductivities λ_k are given by polynomial fits valid over a range of temperatures, or to be precise, by the exponential of a polynomial in powers of the logarithm of temperature. The mixture viscosity is calculated by a similar semi-empirical formula. The mixture-averaged diffusion coefficient is defined by

$$D_{km} = (1 - Y_k) \Big/ \sum_{l\in\mathcal{S},l\neq k} X_l/\mathcal{D}_{kl} \ , \tag{20}$$

where $\mathcal{D}_{kl} = \mathcal{D}_{lk}$ is the binary diffusion coefficient of species k into species l, or vice-versa. As with the other transport coefficients, the building blocks for the mixture-averaged diffusion coefficient, the binary species diffusion coefficients, are functions of temperature, with $\log \mathcal{D}_{kl}$ being approximated by a polynomial in powers of $\log T$. Although the mixture-averaged diffusion model represents an enormous simplification as compared with the full multicomponent diffusion model, it is important to stress that even using this simpler model can come at a considerable cost. Since the computational expense of evaluating all the D_{km} scales roughly as the square of the number of species in $\mathcal{S}$, chemistry models with a large number of species can lead to flame calculations in which a significant proportion of the CPU time is spent in the transport module of the code.

Appendix F

Chemistry Models

One of the remaining frontiers of combustion science is the design of reliable detailed kinetic models for realistic fuels, e.g., transportation, and the eventual deployment of such models to study challenging, poorly understood burning regimes in technologically relevant flame systems, for instance, those characterized by pollutant and particulate formation or by strong interactions between fluid dynamic and chemical effects. A key requirement for progress on these fronts continues to be the development of numerical codes that can handle such detailed chemistry models. The challenge arises both from the size of the models and the amount of computation they demand, and from the wide disparity of time scales supported by them, which leads to the problem of "stiffness."

The reaction set of an arbitrarily complex, detailed chemistry model can be written in symbolic form as

$$\sum_{k\in\mathcal{S}} \nu'_{ki}\mathcal{X}_k \rightleftharpoons \sum_{k\in\mathcal{S}} \nu''_{ki}\mathcal{X}_k \ , \qquad i \in \mathcal{R} \ , \tag{21}$$

where k and i are the species and reaction indices, respectively; ν'_{ki} and ν''_{ki}, the stoichiometric coefficients of reactant k in both forward and reverse reaction i; $\mathcal{X}_k$, the chemical symbol of species k; and $\mathcal{R}$, the set of N_{reac} reactions. A rate of progress Q_i may be defined for each elementary reaction i according to the law of mass action, and the sum of the rates of progress for all reactions involving species k, multiplied by the appropriate net stoichiometric coefficient, gives the molar production rate for this species:

$$Q_i = k_i^f(T) \prod_{k\in\mathcal{S}} \left(\frac{\rho Y_k}{W_k}\right)^{\nu'_{ki}} - k_i^r(T) \prod_{k\in\mathcal{S}} \left(\frac{\rho Y_k}{W_k}\right)^{\nu''_{ki}} \tag{22}$$

$$\dot{\omega}_k = \sum_{i\in\mathcal{R}} \left(\nu''_{ki} - \nu'_{ki}\right) Q_i \ . \tag{23}$$

The forward and reverse rate constants for reaction i are denoted by k_i^f and k_i^r, respectively. These "constants" are not constant at all but rather strongly dependent on temperature, and the relationship for the forward coefficient is modeled by a modified Arrhenius expression:

$$k_i^f(T) = A_i\, T^{\beta_i}\, \exp(-E_i/RT) \ . \tag{24}$$

The pre-exponential factor A_i, the temperature exponent β_i, and the activation energy E_i, all specified by the kinetic mechanism, are typically estimated by experimental techniques and tuned as needed to achieve certain benchmarks, such as the correct prediction of premixed laminar flame speeds or ignition and extinction criteria. Although it is possible to specify Arrhenius parameters separately for the reverse reaction, the Chemkin default is to back out the reverse rate constant from the forward rate constant and the equilibrium constant, with the latter determined from a

thermodynamic calculation [33]. The empirical nature of the Arrhenius model is one reason for this reliance on the equilibrium constant, the formula for which is well founded from a theoretical point of view.

Table I illustrates a sample reaction mechanism for methane-air mixtures. The system includes 16 chemical species and 46 elementary reactions [39]. More complicated mechanisms can contain hundreds of species and thousands of chemical reactions [40]. Detailed theoretical and experimental studies have been undertaken to generate high fidelity networks of elementary reactions that can be used in the prediction of combustion phenomena see, e.g., [41].

TABLE I

Reaction Mechanism Rate Coefficients In The Form $k_f = AT^{\beta}\exp(-E_0/RT)$.
Units are moles, cubic centimeters, seconds, Kelvins and calories/mole.

	REACTION	A	β	E
1.	$CH_4 + M \rightleftharpoons CH_3 + H + M$	1.00E+17	0.000	86000.
2.	$CH_4 + O_2 \rightleftharpoons CH_3 + HO_2$	7.90E+13	0.000	56000.
3.	$CH_4 + H \rightleftharpoons CH_3 + H_2$	2.20E+04	3.000	8750.
4.	$CH_4 + O \rightleftharpoons CH_3 + OH$	1.60E+06	2.360	7400.
5.	$CH_4 + OH \rightleftharpoons CH_3 + H_2O$	1.60E+06	2.100	2460.
6.	$CH_2O + OH \rightleftharpoons HCO + H_2O$	7.53E+12	0.000	167.
7.	$CH_2O + H \rightleftharpoons HCO + H_2$	3.31E+14	0.000	10500.
8.	$CH_2O + M \rightleftharpoons HCO + H + M$	3.31E+16	0.000	81000.
9.	$CH_2O + O \rightleftharpoons HCO + OH$	1.81E+13	0.000	3082.
10.	$HCO + OH \rightleftharpoons CO + H_2O$	5.00E+12	0.000	0.
11.	$HCO + M \rightleftharpoons H + CO + M$	1.60E+14	0.000	14700.
12.	$HCO + H \rightleftharpoons CO + H_2$	4.00E+13	0.000	0.
13.	$HCO + O \rightleftharpoons OH + CO$	1.00E+13	0.000	0.
14.	$HCO + O_2 \rightleftharpoons HO_2 + CO$	3.00E+12	0.000	0.
15.	$CO + O + M \rightleftharpoons CO_2 + M$	3.20E+13	0.000	-4200.
16.	$CO + OH \rightleftharpoons CO_2 + H$	1.51E+07	1.300	-758.
17.	$CO + O_2 \rightleftharpoons CO_2 + O$	1.60E+13	0.000	41000.
18.	$CH_3 + O_2 \rightleftharpoons CH_3O + O$	7.00E+12	0.000	25652.
19.	$CH_3O + M \rightleftharpoons CH_2O + H + M$	2.40E+13	0.000	28812.
20.	$CH_3O + H \rightleftharpoons CH_2O + H_2$	2.00E+13	0.000	0.
21.	$CH_3O + OH \rightleftharpoons CH_2O + H_2O$	1.00E+13	0.000	0.
22.	$CH_3O + O \rightleftharpoons CH_2O + OH$	1.00E+13	0.000	0.
23.	$CH_3O + O_2 \rightleftharpoons CH_2O + HO_2$	6.30E+10	0.000	2600.
24.	$CH_3 + O_2 \rightleftharpoons CH_2O + OH$	5.20E+13	0.000	34574.
25.	$CH_3 + O \rightleftharpoons CH_2O + H$	6.80E+13	0.000	0.
26.	$CH_3 + OH \rightleftharpoons CH_2O + H_2$	7.50E+12	0.000	0.
27.	$HO_2 + CO \rightleftharpoons CO_2 + OH$	5.80E+13	0.000	22934.
28.	$H_2 + O_2 \rightleftharpoons 2OH$	1.70E+13	0.000	47780.
29.	$OH + H_2 \rightleftharpoons H_2O + H$	1.17E+09	1.300	3626.
30.	$H + O_2 \rightleftharpoons OH + O$	2.20E+14	0.000	16800.
31.	$O + H_2 \rightleftharpoons OH + H$	1.80E+10	1.000	8826.
32.	$H + O_2 + M \rightleftharpoons HO_2 + M^a$	2.10E+18	-1.000	0.
33.	$H + O_2 + O_2 \rightleftharpoons HO_2 + O_2$	6.70E+19	-1.420	0.
34.	$H + O_2 + N_2 \rightleftharpoons HO_2 + N_2$	6.70E+19	-1.420	0.
35.	$OH + HO_2 \rightleftharpoons H_2O + O_2$	5.00E+13	0.000	1000.
36.	$H + HO_2 \rightleftharpoons 2OH$	2.50E+14	0.000	1900.
37.	$O + HO_2 \rightleftharpoons O_2 + OH$	4.80E+13	0.000	1000.
38.	$2OH \rightleftharpoons O + H_2O$	6.00E+08	1.300	0.
39.	$H_2 + M \rightleftharpoons H + H + M^b$	2.23E+12	0.500	92600.
40.	$O_2 + M \rightleftharpoons O + O + M$	1.85E+11	0.500	95560.
41.	$H + OH + M \rightleftharpoons H_2O + M^c$	7.50E+23	-2.600	0.
42.	$H + HO_2 \rightleftharpoons H_2 + O_2$	2.50E+13	0.000	700.
43.	$HO_2 + HO_2 \rightleftharpoons H_2O_2 + O_2$	2.00E+12	0.000	0.
44.	$H_2O_2 + M \rightleftharpoons OH + OH + M$	1.30E+17	0.000	45500.
45.	$H_2O_2 + H \rightleftharpoons HO_2 + H_2$	1.60E+12	0.000	3800.
46.	$H_2O_2 + OH \rightleftharpoons H_2O + HO_2$	1.00E+13	0.000	1800.

[a] Third body efficiencies: $k_5(H_2O) = 21k_5(Ar)$, $k_5(H_2) = 3.3k_5(Ar)$, $k_5(N_2) = k_5(O_2) = 0$.

[b] Third body efficiencies: $k_{12}(H_2O) = 6k_{12}(Ar)$, $k_{12}(H) = 2k_{12}(Ar)$, $k_{12}(H_2) = 3k_{12}(Ar)$.

[c] Third body efficiency: $k_{14}(H_2O) = 20k_{14}(Ar)$.

Appendix G

Radiation Model

The final submodel that needs to be specified concerns the divergence of the net radiative flux in the energy equation. In an unconfined geometry, gas radiation acts to cool the flame, typically with non-negligible effects on density, velocity, and reaction rates, as well as a number of other flame properties. Radiative heat transfer is a complicated process involving emission, reabsorption, and scattering of photons in a three-dimensional setting. Since the radiation that passes through a given point in the flow field can originate at any other point and be attenuated in transit between them, the physics must be modeled mathematically by a complicated integral over all space (all directions of propagation) and all frequencies. However, if the reabsorption and scattering of radiant energy can be neglected then the modeling is considerably simplified in what is called the "optically thin" or emission-dominated limit applies, in which case the nonlocal, anisotropic term in the integrand vanishes and the formula for the divergence of the radiative flux reduces to

$$\nabla \cdot \mathbf{q}_{rad} = 4\pi \int_0^\infty K_a(\nu)\, I_b(\nu, T)\, d\nu \ , \tag{25}$$

where ν is a wavenumber variable (i.e., inverse wavelength), K_a is the frequency-dependent absorption coefficient, and I_b is the Planck function giving the spectral radiance emitted from a black body at absolute temperature T.[1] The discretization of this integral in wavenumber-space is guided by the fact that almost all of the radiation absorbed and emitted by molecular gases is associated with a few narrow regions, or "bands," in their spectra. The Planck function is evaluated at the centers of these bands, and is considered to be constant across each of them. The absorption coefficient for the n^{th} absorption band of species k is modeled by a peaked function of a specified bandwidth, whose integral may be expressed as the product of an integrated band intensity and the partial density of this species in the mixture. Values for these intensities (α_{kn}) and the central wavenumbers of the bands ($\nu_{kn}^{(0)}$) are tabulated in [43] for the most optically active species, H_2O, CO_2, and CO. The result is a simple double sum for the radiation term:

$$\nabla \cdot \mathbf{q}_{rad} = 4\pi \sum_k \sum_n \alpha_{kn}\, \rho_k\, I_b(\nu_{kn}^{(0)}, T) \ . \tag{26}$$

This quantity is important because it gives an upper bound on radiative losses in a flame. However, in some conditions, e.g., at high pressures or low strain rates, the gas could be sufficiently dense or the flame sufficiently thick that the optically thin approximation is no longer justifiable. In that

[1] Here the formalism of [42] is used without completely following its notation. In particular, in keeping with [43], ν is used for the wavenumber rather than ω, since ω is very similar to the symbol introduced previously for the molar production rate ($\dot{\omega}$). As it happens, ν is also a common symbol for frequency, which is proportional to but not equal to wavenumber. It is important to keep all these things straight when considering the Planck function so as to avoid confusion. The Planck function is typically expressed in terms of either frequency or wavelength, with the forms differing in part by large constant factors that arise from the change of variables; however, in this work, also following [43], it is expressed in terms of wavenumber as: $I_b(\nu, T) = 2hc^2\nu^3/(\exp(hc\nu/k_BT) - 1)$, where h is Planck's constant, c the speed of light, and k_B the Boltzmann constant.

case, a more complicated radiation model would be necessary, an example of which is presented in [42]. A good general discussion of radiation transport modeling for numerical combustion may be found in [44].

Appendix H

Flammability Limits and Ignition

What distinguishes combustion from fluid mechanics is chemistry. When a fuel, e.g., a hydrocarbon molecule, is heated beyond a given temperature, chemical reactions occur which consumes the fuel in the presence of an oxidizer such as molecular oxygen. The resulting process can relinquish large quantities of heat with a corresponding rise in the temperature of the system. While the ultimate products of complete combustion are carbon dioxide and water, rarely are these the only products that are formed. Instead, the oxidation of a fuel proceeds through hundreds (even thousands) of elementary chemical steps with commensurate numbers of chemical species generated during the process (see *Appendix F*). The combustion of fuels occurs in either a premixed or nonpremixed mode. In the former, the fuel and oxidizer are mixed prior to combustion and in the latter the fuel and oxidizer are separated before combustion takes place. Most practical combustion devices operate (due to safety concerns) in the nonpremixed mode.

On occasion, combustion can occur spontaneously. In such cases combustible matter, such as hay or coal, stored in bulk begins a slow oxidation process (as bacterial fermentation or atmospheric oxidation) under conditions not permitting ready dissipation of heat, e.g., in the center of a haystack or a pile of oily rags. Oxidation gradually raises the temperature inside the mass to the point at which a fire starts. Crops are commonly dried before storage or, during storage, by forced circulation of air, to prevent spontaneous combustion by inhibiting fermentation. For the same reason soft coal is wetted to suppress aerial oxidation.

Arbitrary fuel-air mixtures may or may not burn. The mixture must fall within the flammability limits for the specific fuel. The flammability limit defines the concentrations of fuel vapor that can be ignited and thus sustain combustion. If the mixture falls outside these limits, combustion cannot be sustained. This implies that, if there is too much fuel and not enough oxygen, the mixture will be outside what is termed the rich flammability limit and, if there is too much oxygen and not enough fuel, the mixture will be outside what is termed the lean flammability limit. These limits are fuel and pressure dependent. Figure 2 illustrates an example of flammability limits for methane-air mixtures.

To ignite a fuel-air mixture requires an outside supply of energy. The minimum amount of energy that is needed for combustion of a fuel-air mixture is called the minimum ignition energy. Each fuel has a different minimum ignition energy depending upon the amount of oxygen present. Minimum ignition energies will vary depending upon where in the flammability region the fuel-air mixture falls. Mixtures that are near the rich flammability limit will ordinarily require more energy to ignite than those that fall in between the rich and lean flammability limit. The same concept applies to mixtures near the lean flammability limit. Figures 3 and 4 list minimum ignition energies and the minimum ignition temperatures for a variety of hydrocarbon fuels.

From Figure 4 one can see that the ignition temperature of alkanes, alkenes and alkynes generally occur in the 225C-525C range. Once the temperature of the fuel-air mixture rises above the ignition temperature, the system experiences a rapid temperature increase. This is a direct result of the heat of combustion of the specific fuel. It is defined as the heat released for the complete combustion of a compound in its standard state to form stable products in their standard state, i.e., hydrogen

is converted to water (in its liquid state), carbon is converted to carbon dioxide gas, and nitrogen is converted to nitrogen gas. That is, the heat of combustion, ΔH_{comb}, is the heat of reaction of the following process:

$$C_x H_y N_z O_n(std.) + O_2(g) \rightarrow xCO_2(g) + \frac{y}{2} H_2O(l) + \frac{z}{2} N_2(g)$$

where x, y, z and n are used to balance the equation.

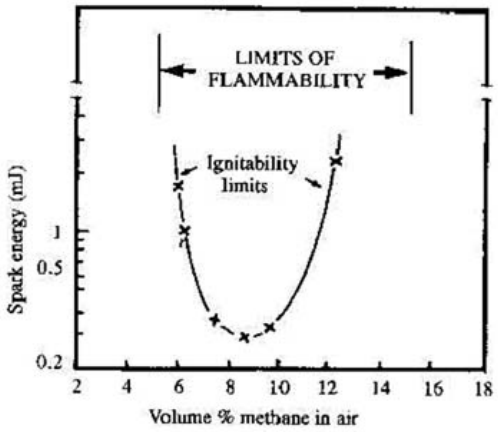

Figure 2 – Flammability limits for Methane. From: Zabetakis, M.G., *Flammability Characteristics of Combustible Gases and Vapors*, Bulletin 627, U.S. Department of the Interior, Bureau of Mines, 1965.

Minimum Ignition Energies

Minimum Ignition Energy for Selected Gases[1]

Chemical	Minimum ignition energy (mJ)
Acetylene	0.020
Benzene	0.225
1,3-Butadiene	0.125
n-Butane	0.260
Cyclohexane	0.223
Cyclopropane	0.180
Ethane	0.240
Ethene	0.124
Ethylacetate	0.480
Ethylene oxide	0.062
n-Heptane	0.240
Hexane	0.248
Hydrogen	0.018
Methane	0.280
Methanol	0.140
Methyl acetylene	0.120
Methyl ethyl ketone	0.280
n-Pentane	0.220
2-Pentane	0.180
Propane	0.250

[1]Data from I. Glassman, *Combustion*, 3d ed. (New York: Academic Press, 1996).

Figure 3 – Minimum Ignition Energy for a variety of hydrocarbon fuels.

Gas or Vapor	Thermal Ignition Temperature (°C)
methane, CH_4	540
propane, C_3H_8	450
n-hexane, C_6H_{14}	225
n-octane, C_8H_{18}	220
ethane, C_2H_6	515
ethylene, C_2H_4	490
acetylene, C_2H_2	305
carbon disulfide, CS_2	90
diethyl ether, $C_2H_5OC_2H_5$	160
hydrogen, H_2	400

Figure 4 – Minimum Ignition Temperatures for a variety of hydrocarbon fuels.

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Report of Dr. Sally Satel MD

Analysis of the role of non-combustible products in tobacco harm reduction

14 June 2022

Sally Satel MD

I. INTRODUCTION

1. Almost one billion people around the world smoke cigarettes daily.[1]

2. Fortunately, smokers who do quit before they reach the age of 40 are very likely to avoid most of the excess mortality associated with smoking, according to the seminal British doctors' study.[2] Indeed, quitting at any age confers a substantial reduction in disease risk compared to continuing smoking, and the longer the period of cessation the greater the reduction in disease risks. According to the US Surgeon General Report on Smoking Cessation, "Although the benefits of quitting are greater the earlier in life that an individual quits, this report confirms that it is never too late to quit smoking. Even persons who have smoked for many years or who have smoked heavily can realize health and financial benefits from quitting smoking."[3] Yet, quit rates are very low, from 3 percent to 12 percent annually, and relapse rates are also high, from 75 percent to 80 percent in the first six months and between 30 percent and 40 percent even after one year of abstinence.[4]

3. Therefore, reduced risk tobacco and nicotine products that provide an alternative to conventional cigarettes and can thereby reduce smoking rates, demand serious attention. Electronic cigarettes (e-cigarettes) and Heat Not Burn ("HNB") devices (together "non-combustibles") present great promise in achieving this goal of tobacco harm reduction by displacing smoking.

E-cigarettes

4. By way of background, e-cigarettes are battery-powered devices that heat a flavored solution containing nicotine and convert it into an inhalable, or "vape-able," aerosol. These products show great promise as reduced risk alternatives for smokers who would not otherwise quit. Because e-cigarettes do not burn tobacco, they emit a mere fraction of the carcinogens and hazardous gases than do conventional cigarettes.

Heat Not Burn Products

5. HNB products are another form of non-combustible cigarette alternatives. Unlike e-cigarettes, HNB products do contain tobacco, but do not burn it. Instead, they warm the material enough to create an aerosol the user then inhales. In the absence of combustion, the aerosol produced by HNB products contains far fewer and lower levels of toxic chemicals than cigarette smoke.

Tobacco Harm Reduction

6. The philosophy of "tobacco harm reduction" is centered around the goal of reducing harm to the health of cigarette smokers who are unwilling to stop using nicotine through traditional methods (primarily cigarette smoking) by encouraging the substitution of other non-combustible nicotine products.

II. BACKGROUND, MANDATE AND SUMMARY CONCLUSIONS

7. I am a physician specializing in addiction psychiatry and am a resident scholar at the American Enterprise Institute with expertise in public health policy, addiction,

and harm reduction. I also serve on the current National Advisory Board of the Substance Abuse and Mental Health Services Administration and in 2019 I testified before the US House Labor, Health, and Education Appropriations Subcommittee on teen vaping and balancing the protection of youth with the health of smokers. Further details of my qualifications and experience are contained in my CV which is attached to this report.

8. I have been asked by British American Tobacco to provide an opinion based on my medical background, expertise, and review of the scientific literature and scholarship on the role of non-combustible products in tobacco harm reduction. I have been closely following the development of e-cigarettes and HNB products as disruptive technologies in public health. For this expert report, I have been asked to address five questions.

9. The first concerns the comparative risks of e-cigarettes and HNB products compared to conventional cigarettes. Although e-cigarettes and HNB products have not been in use long enough for there to be long-term epidemiological data concerning any long-term health risks, experts consider e-cigarettes and HNB products to be much safer than conventional cigarettes. Studies, in fact, show a dramatic reduction in exposure to toxicants almost to the level of non-smokers or quitters – accounting for the documented improvements in the health of smokers who switch to e-cigarettes and HNB products.

10. The second point of my inquiry is conceptual: why does the advancement of public health depend upon understanding comparative risk rather than absolute risk? In this report, comparative risk compares health hazards of non-combustibles to hazards of combustible tobacco products, whereas absolute risk evaluates the risk of non-combustibles compared to not using any nicotine products at all. It is a tenet of sound health policy that people make considered choices for themselves. This is only possible if experts from the fields of public health and medicine communicate the most accurate information on the costs and benefits of alternatives.

11. The third question is whether non-combustibles are an effective substitute for conventional smoking. In this report, I show how different types of scientific evidence coalesce to demonstrate that, while not marketed as smoking cessation devices, many smokers use non-combustibles to quit smoking. The evidence includes data derived from large populations, from questionnaires administered to large groups of people, and from randomized controlled trials (the latter showing about twice the smoking cessation efficacy compared to nicotine replacement therapy ("NRT") in controlled conditions). In particular, vaping is now the most popular and successful product used for quitting smoking.

12. The fourth domain of concern is flavors and their role in encouraging smokers to switch from conventional cigarettes to e-cigarettes and HNB products. Data consistently show that flavors are crucial to adults' preference of vaping over smoking and to easing the transition from combusted tobacco to aerosolized nicotine. At the same time, surveys of youth who have vaped reveal that flavors are not the primary attraction of vaping.

13. Fifth, I address the concern that e-cigarette (and to a lesser extent, HNB products) use, particularly among young people, serves as an introduction to future cigarette smoking (the gateway hypothesis). Evidence from the US and the UK

demonstrates that regular use of e-cigarettes by youth is rare and that the so-called gateway effect has not materialized. To the contrary, studies show that teens in the US now smoke cigarettes at the lowest rates in history and have experienced unprecedented decreases in smoking prevalence precisely during the period of vaping's popularity. Thus, far from serving as a gateway to smoking, teen vaping use where it does occur appears to serve as a substitute for teen smoking. In this regard, I dispel anxiety surrounding the gateway theory by citing large-sample studies that find a common vulnerability to both smoking and vaping. In other words, youth who choose to vape share common risk factors with youth who smoke, and, if not for e-cigarettes, may have smoked cigarettes instead. Furthermore, the logic of smoking patterns is inconsistent with a causal relationship between vaping and smoking. After all, if e-cigarettes led youth to start smoking, we would have seen an increase in smoking following the emergence of e-cigarettes. Yet, in reality, the opposite has happened. As experimentation with e-cigarettes and, to a much lesser extent, regular youth vaping has increased, smoking has declined. Finally, in response to those who contend that non-combustible use has "re-normalized" smoking, reassurance is at hand: data from two countries that have embraced e-cigarettes to varying degrees, the UK and the US, show youth and adult smoking rates are at their lowest levels ever.

14. Lastly, I discuss the implications of this current scientific knowledge for public health policy. Naturally, there is more to learn about current, and future, lower-risk products. Quoting Sir Austin Bradford Hill, the late English epidemiologist and statistician,[5] "All scientific work is incomplete - whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have or postpone the action that it appears to demand at a given time."[6] Thus far, we have amassed considerable knowledge about e-cigarettes and HNB products. Data consistently confirm a relative decrease in harmful exposure to toxicants associated with non-combustible products compared to continued smoking in addition to the improvement in users' pulmonary and cardiovascular health, combined with the effectiveness of non-combustible products as substitutes for conventional cigarettes.

15. Accordingly, it is my confident medical and scientific opinion that policymakers should make e-cigarettes and HNB products widely accessible to adult smokers so that the products can fulfill their public health potential. By no means should they be banned or subject to overly limiting caps on nicotine strength, flavor bans, restrictive tobacco product regulation, or taxation at the high rates that apply to combustible cigarettes.

III. COMPELLING EVIDENCE DEMONSTRATING THAT E-CIGARETTES AND HNB PRODUCTS ARE SUBSTANTIALLY LESS HARMFUL THAN CONVENTIONAL CIGARETTES

<u>E-cigarettes</u>

16. Cigarettes contain roughly 7,000 chemicals, including 70 known human carcinogens, carbon monoxide, nitrogen oxides, and other gaseous constituents. Several analyses of e-cigarette aerosol show that while it contains some toxins and carcinogens, they are far fewer in number and are present at much lower levels than those found in cigarette smoke. The toxicants in conventional

cigarettes, for example, exceed that of e-cigarette aerosol by two orders of magnitude.[7] In other words, some toxicants in conventional cigarettes, for example, exceed those in e-cigarette aerosol "by 100-fold." As expected, a growing body of clinical evidence demonstrates that adult smokers' exposure to carcinogens and toxicants falls substantially following their transition to vaping. In fact, those levels are comparable to those measured in unaided, 'cold-turkey' quitters.[8]

17. One of the earliest studies on e-cigarette aerosols appears in the journal *Tobacco Control* in 2012.[9] Researchers at Roswell Park Cancer Institute screened the vapor generated from 12 brands of e-cigarettes, for four groups of potentially toxic and carcinogenic compounds: carbonyls (such as formaldehyde and acetaldehyde), volatile organic compounds, and nitrosamines. The study found that heavy metals, such as cadmium, lead, and nickel may be present but in amounts and forms considered nontoxic.[10] "We found that the e-cigarette vapors contained some toxic substances," the authors write, going on to note that, "the levels of the toxicants were 9–450 times lower than in cigarette smoke and were, in many cases, comparable with trace amounts found in the reference product."

18. In 2015, Public Health England ("PHE") released a high-profile report on e-cigarettes estimating that vaping is around 95 percent safer than smoking.[11] Analysts derived this estimate from data demonstrating that the constituents of cigarette smoke that harm health – including carcinogens – are either absent in e-cigarette vapor or, if present, they are mostly at levels much below 5 percent of smoking doses (mostly below 1 percent and far below safety limits for occupational exposure).[12] "While vaping may not be 100 percent safe, most of the chemicals causing smoking-related disease are absent and the chemicals which are present pose limited danger," the agency stated. In 2016, the Royal College of Physicians echoed the key findings of PHE: "[a]lthough it is not possible to quantify the long-term health risks associated with e-cigarettes precisely, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure."[13]

19. In 2018, PHE updated the evidence in a review of both e-cigarettes and HNB products. "Our new review reinforces the finding that vaping is a fraction of the risk of smoking, at least 95 percent less harmful, and of negligible risk to bystanders [save for those with asthma or other respiratory conditions, who are vulnerable to myriad ambient irritants]. Yet over half of smokers either falsely believe that vaping is as harmful as smoking or just don't know," they summarize.[14]

20. Similarly, in 2018, the U.S. National Academies of Sciences, Engineering, and Medicine, wrote that, "Laboratory tests of e-cigarette ingredients, in vitro toxicological tests, and short-term human studies suggest that e-cigarettes are likely to be far less harmful than combustible tobacco cigarettes."[15]

21. The UK Committee on Toxicity's ("COT") 2020 report, which addressed both exposure to users and ambient exposure, found that in users, constituents such as propylene glycol and glycerol elicited a "low level of concern." Regarding "other constituents," the report states that, "Data from biomonitoring studies support the conclusion that exposure to levels of tobacco-related toxicants

associated with E(N)NDS use is lower than from conventional cigarette smoking, but not as low as in non-users of tobacco products." Overall, the COT concluded: "The use of E(N)NDS products, produced according to appropriate manufacturing standards and used as recommended, as a replacement for [combustible cigarette] smoking, is likely to be associated with a reduction in overall risk of adverse health effects, although the magnitude of the decrease will depend on the effect in question."

22. Evidence also indicates improvements in cardiovascular and pulmonary function in cigarette smokers who switch exclusively to e-cigarettes, according to a recent review article in the *American Journal of Public Health.*[16] Other reports show that tests of lung and vascular function and hypertension[17] find improvement in smokers who switch to e-cigarettes.[18] In terms of perceived wellbeing, exclusive users of e-cigarette, who were largely former smokers, report fewer respiratory symptoms than do cigarette smokers and dual users.[19]

Heat Not Burn Products

23. HNB products are gaining popularity and because they do not burn tobacco, they do not impose health risks comparable to traditional combustible tobacco products. In a 2018 "evidence review" by Public Health England,[20] the authors stated that, "Compared with cigarette smoke, heated tobacco products are likely to expose users and bystanders to lower levels of particulate matter and harmful and potentially harmful compounds. The extent of the reduction found varies between studies."

24. In July 2020, the US Food and Drug Administration (FDA) authorized the marketing of a HNB product. Makers were allowed to claim that the product significantly reduces the production of harmful and potentially harmful chemicals, and that scientific studies have shown that switching completely from conventional cigarettes to the product significantly reduces the user's exposure to harmful or potentially harmful chemicals. Mitch Zeller, J.D., director of the FDA's Center for Tobacco Products was quoted as follows in the agency press release: "Data submitted by the company shows that marketing these particular products with the authorized information could help addicted adult smokers transition away from combusted cigarettes and reduce their exposure to harmful chemicals, but only if they completely switch."21

25. HNB products produce higher levels of toxicants than do e-cigarettes, but the levels are still considerably lower than found in cigarette smoke.22 The published results of laboratory testing of a HNB product by Japanese researchers, found the concentration of tobacco-specific nitrosamines ("TSNAs") was one-fifth and carbon monoxide (CO) was one-hundredth of those of conventional combustion cigarettes.23 A toxicological product assessment conducted found levels of aldehydes at approximately 80 percent–95 percent lower than cigarettes and volatile organic compounds approximately 97 percent–99 percent lower.24 Another toxicological study using a "margin of exposure" analysis reported that a HNB product reduced the risks from exposure to 9 out of the 20 most toxic compounds in tobacco comparing the use of HNB with smoking conventional tobacco products.25

26. Ikonomidis and colleagues 2021[26] randomized 50 smokers to regular cigarettes and a HNB product. Users of the HNB product showed less compromise in endothelial function, arterial stiffness, myocardial deformation, oxidative stress, and platelet activation both acutely and after 1 month of switching exclusively to HNB use. In late 2021, an international team of researchers confirmed in *Nature* that almost 80 percent of cytotoxic effects on bronchial epithelial cells are due to volatile compounds in the vapor phase of smoke and found "no cytotoxicity on bronchial epithelial cells with any [HNB or e-cigarette] product."[27] Examining separately carbon monoxide in a human subject clinical trial, 12 adult smokers (6 male, 6 female) experienced no elevation in carbon monoxide levels, a risk factor for cardiovascular disease, measured at intervals up to 45 minutes post-use.[28]

27. In addition, a 2021 randomized control trial performed in the U.K. found that biomarkers of exposure and potential harm are reduced when smokers switch from smoking cigarettes to exclusive use of a tobacco heating product.[29] The product used in the study was glo THP device and Neostick tobacco consumables. After 180 days of observation, biological markers of exposure and harm in the smoking group remained stable, while glo users' levels of most biological markers of exposure, and thus harm, reduced significantly, becoming similar to those in controls abstaining from cigarette smoking.

IV. SOUND HEALTH POLICY REQUIRES FOCUS ON COMPARATIVE RISKS, NOT ABSOLUTE RISKS OF NON-COMBUSTIBLES IN A VACUUM

28. What are clinicians, policymakers, and smokers to make of claims that e-cigarettes and HNB products are "not without harm"?[30] To be sure, vaping and HNB use are not risk free. Yet, the advancement of public health requires evaluating the effects of non-combustible products in comparison to the impact of conventional cigarettes. Analysis of such comparative risk is critical to a harm reduction framework. Indeed, it is an ethical imperative for the public health and medical fields to provide smokers information on less hazardous ways of consuming nicotine and to encourage those smokers who would otherwise continue to smoke, to try non-combustibles even if these less hazardous forms are not risk-free.

29. Unfortunately, a number of high-profile international agencies mislead the public about non-combustibles by presenting the absolute risks only. Doubtless, health experts must be transparent about any negative consequences of e-cigarettes and other non-combustibles, but when they present such information inaccurately and, in a vacuum, that is, without comparing the comparative risks of these products to combustible cigarettes, they can do more harm than good.

30. The World Health Organization ("WHO") prominently displays the following warnings in its materials for the public: "ENDS [Electronic Nicotine Delivery Systems] contain varying amounts of nicotine and harmful emissions"; "ENDS expose non-smokers and bystanders to nicotine and other harmful chemicals"; and "There is a risk of the devices leaking, or of children swallowing the liquid, and ENDS have been known to cause serious injuries, including burns, through fires and explosions."[31] The *European Union Scientific Committee on Health, Environmental and Emerging Risks* ("SCHEER") likewise only provides an absolute assessment of harm, in its 2020 report. It warns of a "moderate weight of

evidence for risks of local irritative damage to the respiratory tract and moderate, but a growing level of evidence from human data suggesting that electronic cigarettes have harmful health effects, especially but not limited to the cardiovascular system."[32]

31. These publications stand out for their methodological flaws. Robert Beaglehole, former director of the Department of Chronic Diseases and Health Promotion at the WHO, highlighted these flaws and challenged the validity of the WHO's statements in a December 2020 keynote speech in the U.K. before an audience of e-cigarette researchers.[33] Beaglehole said the WHO had "lost its way" and urged leadership to stop obstructing harm reduction efforts and recommended an independent inquiry into the agency's leadership.[34] Likewise, the SCHEER report flouted the tenets of sound public health analysis by focusing solely on absolute risk, ignoring extensive scientific literature demonstrating that vape aerosols contain fewer and substantially lower levels of harmful chemicals compared to cigarette smoke.

Examples of exaggerated risk

32. Finding the proper risk-benefit balance is crucial to sound public health policy and harm reduction for smokers, but that evaluation depends upon accurate estimates of the risks and benefits. With respect to risks, it is important to recognize that studies purporting to have identified vaping-related harms too often exaggerate those negative effects. This makes the downside of vaping appear larger than it actually is, and, inevitably, distorts evaluations of risk-benefit trade-offs.

33. Take the example of investigations of cell damage. Experimenters typically expose cells in laboratory settings and assume those settings resemble human physiology. Yet our bodies possess protective and regenerative mechanisms that can minimize the impact of exposure in real life. Thus, naive researchers may over-interpret the results and conclude that their findings are of actual clinical relevance. What's more, such *in vitro* studies sometimes use excessive exposures that fail to correlate with human experience and/or neglect to expose the cells to cigarette smoke as a comparison condition.

34. In the realm of human subject research, the media tend to disseminate worrisome findings under alarmist headlines. Notable examples of flawed research include a January 2015 report in the *New England of Medicine* entitled "Hidden Formaldehyde in E-Cigarette Aerosols."[35] The authors detected formaldehyde in e-cigarette vapour after heating a vaping device to a high voltage setting. Extrapolating from this finding the authors suggested that long-term vaping is associated with an incremental lifetime cancer risk of five to 15 times as high as the risk associated with long-term smoking. However -- and this is key -- no user would ever actually heat an e-cigarette high enough to produce the recorded levels of formaldehyde in the study. The resultant vapor (known as a "dry puff") would be intolerably irritating to the throat. Indeed, when the *NEJM* researchers tested the same device at a voltage level normally used by vapers they detected no formaldehyde.[36] In response, two experts made a formal complaint to the *NEJM* calling for retraction of the paper; forty additional experts wrote a supporting letter.[37] The plea for retraction was unsuccessful, but the journal *Addiction* published the complaint under the title, "Research letter on e-

cigarette cancer risk was so misleading it should be retracted."[38] PHE also corrected the misinformation surrounding the formaldehyde study in its 2015 "evidence update."[39]

35. In February 2020, the *Journal of the American Heart Association* retracted an article purporting to show that vaping increased the risk of heart attacks[40] — but not until other scientists argued strenuously with the journal editors to withdraw it from the scientific literature because its findings were false and invalid.[41]

36. A recent report in the *American Journal of Preventive Medicine* sought to determine a possible association between vaping and chronic lung disease.[42] Researchers used government data from a cohort of smokers and vapers that were collected at three intervals over a four-year period. At each interval, researchers asked subjects whether they had been diagnosed with chronic pulmonary disease. Many of the vapers who did not report disease at the first interval went on to report it subsequently, leading the authors to conclude that e-cigarettes constituted a risk for chronic obstructive pulmonary disease, bronchitis, and asthma. Confounding the results was the fact that over 99 percent of the subjects studied were former smokers or dual users (that is, they vaped and smoked), strongly suggesting that they had chronic lung problems long before the study began, even if those conditions were not formally diagnosed. A subsequent analysis of the same data that took into account whether the subjects were never smokers, former smokers, or current smokers, found that current or former users of e-cigarettes who had never smoked cigarettes had no greater prevalence of respiratory disease than those who had never smoked combustible tobacco and who had never used e-cigarettes.[43] In short, vaping did not confer added risk for the studied respiratory illness compared with people who neither vaped nor smoked.

37. Lastly, consider an unpublished conference presentation publicized by a press release in 2021 by the *American Heart Association,* AHA. The study reported a fifteen percent higher stroke risk at a younger age for e-cigarettes users than for traditional smokers. Although only an abstract, not a peer-reviewed journal article, and therefore preliminary, the finding garnered significant media attention. A number of experts, however, were quick to highlight the shortcomings based on the abstract, calling attention to three facets of the study: (1) that a number of e-cigarette users in this cohort – likely a large segment -- were smokers who may have switched to vaping only *after* they suffered a stroke; (2) that no biologically plausible hypothesis could explain how e-cigarettes could increase the risk of stroke at young ages but decrease it in the older groups, as the study found; and (3) that vapers in this study were overall less likely to have strokes than individuals who continued to smoke – a key, and expected, result that the authors obscured in the presentation of findings.[44] The authors withdrew the abstract and press release, prior to the AHA conference.[45]

<u>Nicotine</u>

38. Nicotine as a chemical substance deserves attention in the context of risk-benefit calculus because the public regularly considers it to be a high-risk component of vaping. Not so. Nicotine is the addictive constituent in tobacco but it is the other constituents of tobacco smoke, not nicotine itself, that primarily cause disease in cigarette smokers' consumption.[46] Nicotine is not carcinogenic.[47] In general,

"nicotine plays a minor role, if any, in causing smoking-induced diseases," according to Neal Benowitz MD of the UCSF Center for Tobacco Control, Research, and Education in the *New England Journal of Medicine*.[48] However, the public tends to misconstrue the risks of nicotine as being the same or similar to the risks of smoking tobacco.

39. Even many physicians do not know these facts. For example, a survey of 826 full-time faculty members in the schools of medicine, public health, dentistry and nursing at the University of Louisville (US) found that 38 percent believed that nicotine, separate from smoking, is a high-risk factor for heart attack and stroke.[49] Thirty-eight percent ranked nicotine a high-risk factor for cancer of all kinds and another 37 percent rated the risk of nicotine as moderate; and for oral cancer, the percentages were 32 percent and 40 percent, respectively. In a 2019 survey of 256 European Union trainees in public health, the vast majority of respondents believed nicotine contributes significantly to disease. Over four-fifths (82.2 percent) associated nicotine with all smoking-related diseases, 59.1 percent indicated that nicotine is an important factor in the development of lung cancer, 62.1 percent thought nicotine was involved in vulnerability to cancer in other organs, and 72.7 percent considered it responsible for atherosclerosis.[50]

Consequences of Exaggerated Risks

40. The stock warning issued by critics of tobacco harm reduction is that "vaping is not safe." This is true but misleading. Relative safety compared to the grave dangers of smoking is what smokers need to know. Worse, otherwise respected agencies such as state departments of public health, health non-profits (such as the American Lung Association and the American Academy of Pediatricians),[51] and even some medical and public health schools, have disseminated information that is outright false. Examples include the warning that e-liquid has been shown to cause a very serious illness called "popcorn lung," and to raise the risk for heart attack and chronic obstructive pulmonary disease.[52]

41. Last January, for example, the American Heart Association posted a page called "Is vaping safer than smoking?"[53] Its answer: "many downsides, few potential upsides." Among other groundless, contrary-to-data claims it tells readers: "E-cigarettes' biggest threat to public health may be this: The increasing popularity of vaping may "re-normalize" smoking, which has declined for years." A more general content analysis of media coverage reveals bias as well. For example, a content analysis of e-cigarette topics and themes covered in US news articles from 2015 to 2018 found that 70 percent of articles on vaping mentioned e-cigarette risks, while only 37 percent noted the potential benefits.[54]

42. Over time, these presentations of the alleged risks of e-cigarettes have influenced adult public opinion. In 2012, the Longitudinal Health Information National Trends Survey conducted by the National Cancer Institute found that 39 percent of respondents believed that e-cigarettes were "less harmful" or "much less harmful" than smoking. [55] The next year, 40 percent held those beliefs.[56] That ascendant trajectory, unfortunately, started to turn down in 2014, eventually declining to 17 percent in 2018 and to 14.8 percent in 2019.[57] A 2019 Reuters poll found that 63 percent of Americans disagreed with the statement that "vaping is healthier than traditional cigarettes," a 16 percentage point increase from the spring of 2016.[58] In the U.K., public perception of vaping's advantage relative to

smoking began to decline after 2015, according to the Smoking Tool Kit Study,[59] which tracks national smoking patterns and cessation-related behavior among all adults. Between 2013 (when tracking on vaping began) and 2015, over half of respondents endorsed e-cigarettes as "less harmful." In 2017, 44.2 percent perceived vaping as less harmful than smoking.[60] In 2020, 29 percent of current smokers believed vaping was less harmful than smoking.[61]

43. PHE's March 2020 evidence update[62] found that: "[p]erceptions of harm from vaping among smokers are increasingly out of line with the evidence. The proportion who thought vaping was less harmful than cigarettes declined from 45% in 2014 to 34% in 2019. These misperceptions are particularly common among smokers who do not vape." The report also concluded that: "increasingly incorrect perceptions among the public about the harms of vaping could prevent some smokers using vaping products to quit smoking." PHE's e-cigarette evidence update report, published in February 2021, also found that: "[p]erceptions of the harm caused by vaping compared with smoking are increasingly out of line with the evidence" and recommended that: "[m]isperceptions of the relative harms of smoking and vaping should be addressed."[63]

44. A University College London study[64] reviewed the association between changes in harm perceptions and e-cigarette use among current tobacco smokers in England between 2014 and 2019. The authors found that for every 1 percent decrease in the mean prevalence of current tobacco smokers who endorsed the belief that e-cigarettes are less harmful than combustible cigarettes, the mean prevalence of e-cigarette use decreased by 0.48 percent. The authors' state: "[…] our results highlight the need for an increase in media portrayals and public health campaigns focusing on the reduced health harms by switching from combustible tobacco to e-cigarettes."

45. In sum, exaggerating the risks of non-combustible tobacco and nicotine products undermines public health goals of moving smokers away from conventional cigarettes to less harmful products including e-cigarettes and HNB products.

V. COMPELLING EVIDENCE THAT E-CIGARETTES AND HNB PRODUCTS REDUCE SMOKING

46. A number of esteemed health agencies have attested to the reduced toxicity of non-combustibles relative to conventional cigarettes. They have also urged smokers to try non-combustibles when other options to quit smoking conventional cigarettes have failed. For example, in 2020, New Zealand's Ministry of Health announced the following: "Evidence is growing that vaping can help people to quit smoking," and that "Stop smoking services must support smokers who choose to use vaping products to quit." The Ministry also "considers [that] vaping products could disrupt inequities and contribute to Smokefree 2025."[65]

47. Similarly, last year the Royal College of Physicians issued a forthright statement: "E-cigarettes are an effective treatment for tobacco dependency and their use should be included and encouraged in all treatment pathways."[66]

48. In addition, in its annual "evidence update" of 2021, Public Health England also endorses vaping as a means to stop smoking cigarettes. The 2021 PHE update found that vaping products are the most popular quit aid used by smokers and reported that vaping is positively associated with quitting smoking successfully. Similarly, the UK National Health Service in 2017 reported that over 50,000

smokers in the UK stopped smoking with a vaping product and that "[a]lternative nicotine delivery devices, such as nicotine vaping products, could play a crucial role in reducing the enormous health burden caused by cigarette smoking."[67] In addition, an early 2020 posting from the U.S. National Institutes of Health -- a research update rather than a report or statement from the agency -- acknowledged that "e-cigarette use may lead some to quit traditional cigarettes."[68]

49. As discussed below, and notwithstanding the e-cigarettes are not marketed as smoking cessation products, there is wide-ranging scientific support that demonstrates the value of non-combustibles in reducing smoking.

E-cigarettes

50. Population studies -- retrospective analyses of large groups of individuals -- analyze changes in rates of smoking or cessation over time. Such analyses are important in showing the association between e-cigarette use and smoking cessation. With respect to e-cigarette use, they show dramatic declines in smoking prevalence that coincide with population uptake of vaping.

51. For example, research from the CDC published in 2017 found that a greater percentage of smokers seeking to quit substituted e-cigarettes in place of the nicotine patch, nicotine gum, or other FDA-approved cessation aids. [69] Subsequent data discussed below, also suggest that the preference translates into more successful quitting.

52. Many studies have examined the impact of e-cigarette use on smoking. A representative sample follows.

53. A CDC study published in 2020 found that 15.1 percent of current exclusive users of e-cigarettes reported recent successful smoking cessation for 6 months or longer.[70] Those data, collected in 2018, exceeded both the 3.3 percent quit rate for people using other non-cigarette tobacco products, and the 6.6 percent quit rate for those using no tobacco products. Notably, 7.1 percent of US adult smokers reported recent successful quitting in 2018, thus e-cigarettes use produced twice the quitting rate of all adult smokers that year.

54. A 2019 report in *Addiction* used cross-sectional survey data collected in the UK monthly between 2006 and 2018 to reveal a near doubling of self-reported cessation among users of e-cigarettes or varenicline compared with other cessation products. "There was little evidence of benefits of using other cessation aids," the authors concluded.[71]

55. Late in 2021, a report published in *JAMA Network Open*, found that smokers who started vaping daily were multiple times more likely to quit than those who never used e-cigarettes.[72] Specifically, 5.8 percent of adult daily cigarette smokers who were not using e-cigarettes and had no plans to ever quit smoking were, in fact, not smoking cigarettes at all at follow-up. By comparison, 28 percent of those who vaped daily, without the intention to quit, were smoke-free. The data comprised about 1,600 smokers from the FDA's Population Assessment of Tobacco and Health (PATH) Study (2014-2019) who, notably, did not plan to quit. "These findings call for consideration of smokers who are not planning to quit

when evaluating the risk-benefit potential of e-cigarettes for smoking cessation in the population," the authors summarized.

56. International findings are comparable and point, as well, to the strong association between vaping and a higher propensity to quit smoking. The 2017 Eurobarometer survey, for example, recorded the duration of smoking cessation for former smokers as well as smoking duration for both current and former smokers across the European Union ("EU"). Farsalinos and colleagues classified smokers according to quit duration to help overcome the problem of analyzing all former smokers, many of whom had quit long before e-cigarettes were available, as one group. Their survey analysis revealed that current daily e-cigarette use in the EU was rare among former smokers of greater than 10 years and was positively associated with recent (5 years or fewer) smoking cessation. Former daily e-cigarette use was also positively associated with recent 2 years or fewer smoking cessation.[73] Farsalinos encapsulated the findings: "we found a strong association between current daily e-cigarette use and being a former (rather than a current) smoker. Specifically, we found that daily e-cigarette use was associated with 5-fold higher odds of having quit smoking in 2015-2017, and with 3-fold higher odds of having quit smoking in 2012-2015. Another important finding of the study was that e-cigarette use was extremely rare among former smokers who had quit before the availability of e-cigarettes, showing that e-cigarettes do not result in relapse to an inhalational habit for these former smokers."[74] The 2020 Eurobarometer study shows that 58 percent of European smokers or ex-smokers who use, or have used, e-cigarettes and/or heated tobacco products say that these products have helped them to either quit or reduce smoking.[75]

57. In Australia, a nationally representative sample of 3,868 adult smokers in Australia found that daily e-cigarette use was strongly associated with smoking reduction/cessation, but occasional use was not.[76]

58. In addition to population studies like those outlined above, a number of randomized clinical trials also provide further confirmatory evidence of the effectiveness of e-cigarettes in helping smokers to quit cigarettes. Importantly, randomized clinical trials give insight into causality – if variable X is manipulated will outcome Y change? – as opposed to observations made in cross-sections or over time. For example, a year-long study led by Peter Hajek, director of the Wolfson Institute of Preventive Medicine's Tobacco Dependence Research Unit at Queen Mary University of London, randomized 886 smokers to various cessation methods. All subjects were motivated to quit. Those randomized to e-cigarettes were 80 percent more likely to abstain from cigarettes for at least a year (18 percent) compared with those who used a range of NRTs (patch, gum, lozenge, nasal spray, inhalator, mouth spray, mouth strip, and microtabs at 9.9 percent).[77] The findings appeared in 2019 in the *New England Journal of Medicine* and garnered considerable scientific and media attention.

59. The following year, in a six-month trial conducted in New Zealand, researchers randomized 1,124 people to one of three groups: nicotine patches (21 mg) only, patches plus a nicotine e-cigarette (18mg/L), or patches plus a nicotine-free e-cigarette. Half of the participants in the patch only group withdrew or were lost at follow-up by 6 months, compared to just under one-third of both of the other groups. At six months, 2 percent of the patch-only group maintained continuous

abstinence from smoking, as verified by carbon monoxide testing, compared with 4 percent in the patch plus nicotine-free device and 7 percent in the patch plus nicotine-containing e-cigarette.[78]

60. In 2021, Jonathan Foulds, a Professor of Public Health Sciences and Psychiatry Penn State University, and his team published the results of a randomized trial of 520 smokers assigned to one of four 24-week conditions. [79] The study subjects received either (1) a vaping device with no nicotine, (2) with 8 mg/ml nicotine, (3) with 36 mg/ml nicotine, or (4) a cigarette-shaped tube containing no nicotine as a cigarette substitute. The subjects reported being motivated to reduce nicotine consumption but were not planning to quit consuming nicotine. At 24 weeks, significantly more participants in the 36 mg/ml condition (10.8 percent) than in the 0 mg/ml (.8 percent) condition or the "tube" condition (3.1 percent) were abstinent from cigarettes. Among the set of subjects in the 8 mg/ml condition, 4.6 percent were abstinent. The authors concluded that if smokers continued to vape with cigarette-like nicotine delivery, a greater proportion completely switched to an e-cigarette, as compared with placebo or a cigarette substitute.

61. A number of reviews of randomized trials have also concluded that e-cigarettes are more effective in helping smokers quit.

62. For example, in September 2021, the *Cochrane Collaboration* published an update to its ongoing review into the effect and safety of using e-cigarettes to help smokers achieve long-term smoking abstinence. This version of the report assessed the results of 61 studies, representing 16,759 participants, of which 34 studies are randomized controlled trials. The authors found that "[m]ore people probably stop smoking for at least six months using nicotine e-cigarettes than using NRT (4 studies, 1,924 people), or nicotine-free e-cigarettes (5-cigarettes, 1,447 people)." It further noted that, "Nicotine e-cigarettes may help more people to stop smoking than no support or behavioural support only (6 studies, 2,886 people)." The authors also found no evidence of harm from nicotine e-cigarettes based on a two year follow up period.[80]

63. In 2021 an Austrian team reviewed 12 randomized controlled trials studies encompassing 8,512 participants and found that "pooling current evidence points toward a potential for e-cigarettes as a smoking cessation tool."[81] Across the studies, e-cigarettes containing nicotine were compared with non-nicotine versions or with established smoking cessation interventions (NRT and or counseling) published between January 2014 and June 2020. The results, which appeared in *Nicotine & Tobacco Research,* indicated that e-cigarettes performed as well if not better than standard interventions. "The proportion of smokers achieving abstinence was 1.71 (95 CI: 1.02–2.84) times higher in nicotine EC users compared with non-nicotine EC users. The proportion of abstinent smokers was 1.69 (95 CI: 1.25–2.27) times higher in EC users compared with participants receiving NRT. EC users showed a 2.04 (95 CI: 0.90–4.64) times higher proportion of abstinent smokers in comparison with participants solely receiving counseling."

64. Another review published last year by a research group in the Centre for Youth Substance Abuse Research, at the University of Queensland, Australia, included randomized controlled trials that allocated individuals to use nicotine e-cigarettes, compared to those that used licensed NRTs, or a nicotine-free control condition such as receiving placebo (nicotine-free) e-cigarettes or usual

intervention.[82] While noting the need for more high quality studies, the authors found that participants randomised to receive nicotine e-cigarettes were almost 50 percent more likely to remain abstinent from smoking than those who received NRTs. Those randomised to receive nicotine e-cigarettes were twice as likely to remain abstinent from smoking than those in control conditions where no nicotine was supplied.

Heat Not Burn products

65. While the data on HNB products leading to reductions in smoking rates is limited, data indicates that these products are displacing combusted cigarettes in the marketplace. For example, HNB products are becoming very popular in a number of countries, including Japan (where e-cigarettes are not available) and South Korea. A particular appeal of HNB products for Japanese smokers is eliminating the social disapproval of the smell of second-hand smoke.[83] Japan has 90 percent of the global market for HNB products.[84] An analysis by Cummings *et al.* (2020) found a five-fold increase in the annual percentage decline in cigarette sales in Japan following the introduction of HNB products in late 2015. The authors stated: "[b]etween 2011 and 2015, cigarette sales in Japan were declining at a slow but steady pace. However, the pace of decline in cigarette sales accelerated beginning in 2016, corresponding to the introduction of [HNB products] into the marketplace."[85]

66. In South Korea, sales of HNB products increased from 79 million packs in 2017 to 332 million packs in 2018 [86] and are expected to increase 21 percent annually.[87] In other major markets for HNB products, sales increased rapidly from 2017 to 2018 as follows: 30 percent in Italy and over 50 percent in Russia.[88]

67. What emerges from both the population data, observational studies, and randomized-controlled experiments described above is strong and consistent evidence suggesting that non-combustibles improve rates of smoking cessation and lower overall rates of smoking. From a harm reduction perspective, therefore, regulations that promote access to and knowledge of non-combustible products should themselves promote the harm reduction potential of these products, as they grow in popularity.

VI. WHY FLAVORS ARE IMPORTANT TO SMOKING CESSATION

68. The rationale for banning flavors may seem plausible on its face: if teens are attracted to flavors, banning them will dissuade teens from vaping. However, the problem is that limiting the appeal of vaping will also affect adult smokers. These smokers are the very group for whom e-cigarettes are intended. Such smokers also find e-cigarettes with flavor beyond tobacco more appealing than e-cigarettes with tobacco flavor. Also, contrary to popular belief, teens are not primarily drawn to e-cigarettes because of flavors. According to a CDC survey, among students who ever used e-cigarettes, the two most common reasons for first use were "a friend used them" (57.8 percent), and "I was curious about them" (47.6 percent). Flavors came in seventh, at 13.5 percent.[89]

69. Surveys routinely report that vapers strongly prefer fruit flavors over tobacco flavor once they make the shift to e-cigarettes. Classic behavioral theory would predict as much: to prevent relapse, a smoker trying to quit should

dissociate from the taste of smoking. A 2018 preference survey of 20,836 adult vapers in the U.S. found that fruit and dessert flavors are the most popular by far, with only a minority using tobacco flavors – between 10 and 20 percent.[90] Fruit flavors were preferred by over two-thirds of those who were using e-cigarettes on a frequent basis (of whom 15,807, 75.9 percent, had completely switched from smoking cigarettes to using e-cigarettes.) Results indicated that adults who have completely switched from smoking cigarettes to using e-cigarettes in the past 5 years are increasingly likely to have initiated e-cigarette use with vapor products not flavored to taste like tobacco.

70. Observational studies also demonstrate the importance of flavors in assisting smokers to switch to e-cigarettes. A 2020 U.S. cohort study in *JAMA* with 17,929 participants used in waves 1-4 (2013-18) of the Population Assessment of Tobacco and Health Study (collected from 2013 to 2018) found that among adults who smoked and began vaping, the odds of smoking cessation for those using non-tobacco flavors were 2.3 times that of those who used tobacco-flavored e-cigarettes.[91] Notably, flavored e-cigarettes were not associated with greater youth smoking initiation.[92] "Critically, this study's findings suggest that efforts to ban flavored e-cigarettes could increase smoking," the authors caution.

71. A 2021 study published in *Nicotine & Tobacco Research* found that smokers who use flavored vapes to quit smoking were 43 percent more likely to succeed than someone using an unflavored or tobacco-flavored vape.[93] Researchers examined 886 concurrent (at least weekly) users of nicotine-containing vaping products and cigarettes who were first surveyed in 2016 and then successfully re-contacted in 2018. The participants were part of a survey project conducted in Australia, Canada, England, and the United States. Compared with users of tobacco flavors, those vaping "sweet" flavors were more likely to quit smoking between surveys (13.8 percent vs. 9.6 percent). In addition, there was a net shift away from tobacco flavor among those who continued to vape at follow-up.

72. Prohibitions on flavors also have predictable consequences. Users would be likely to resume cigarettes if their preferred flavors are no longer available.

73. A 2021 paper published in *Addictive Behaviors*[94] reports on findings from the 2020 ITC Smoking and Vaping Survey wherein researchers collected data from 851 regular vapers (all current or ex-smokers) across the U.S., Canada, and England. They found that 28.3 percent of respondents reported they would find a way to get their banned flavor(s) and 17.1 percent would stop vaping and smoke instead.

74. A study on teens in the wake of a 2018 San Francisco ban on flavors published last year in *JAMA Pediatrics*[95] drew data from the 2011-2019 Youth Risk Behavior Surveillance System school district surveys. Authors found that San Francisco's flavor ban was associated with more than doubled odds of recent smoking among underage high school students relative to concurrent changes in other districts. "This raises concerns," the researchers caution, "that reducing access to flavored electronic nicotine delivery systems may motivate youths who would otherwise vape to substitute smoking."

75. Similarly, online reports and social media posts describe smokers going back to cigarettes or patronizing black markets, which are breeding grounds for the worst manufacturing practices such as tainted nicotine liquids, defective batteries, and heating coils are accumulating.

76. HNB products are available in tobacco and a limited number of other flavors, including menthol and mint.[96] In light of negligible use of HNB products by teens -- according to the 2021 U.S. National Youth Tobacco Survey, 1.8 percent of U.S. middle and high school students reported ever use of an HNB product, and 0.7 percent reported current use[97] -- concern about motives to use amongst youth has not attracted much attention.

VII. E-CIGARETTES AND HNBS DO NOT SERVE AS A GATEWAY TO SMOKING

77. Understandably, the possibility that non-smoking youth who initiate vaping will then turn to smoking is of vast concern to public health officials, politicians, and parents. Hence, the question of whether e-cigarettes serve as a "gateway" to smoking has been extensively researched, with many tobacco control advocates routinely suggesting this is in fact the case. The EU Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) Final Opinion on Electronic Cigarettes***98*** and the "WHO Report on the global tobacco epidemic 2021: New and Emerging Products" have sounded similar notes of caution that allowing vaping will serve as a "gateway" to initiation to smoking.***99*** As will be discussed below, robust data analyses show that vaping is more of a "gateway" out of a smoking addiction for teens than it is a passage into a new smoking habit for those who have never smoked. Indeed, just as the data suggest that vaping and other non-combustibles reduce smoking by increasing rates of cessation, so too do the data suggest that non-combustibles reduce rates of smoking initiation in adolescents and young adults – the time in life when most smokers start experimenting with cigarettes for the first time.

78. Reassuringly, there is little evidence that teens who vape move on to smoking. Data from the U.S., in fact, shows the exact opposite trend wherein smoking rates of minors have declined at unprecedented speed in the last decade. More specifically, current youth smoking dropped more steeply in the years that teen vaping increased most sharply, between 2013 and 2019, reaching a record low in 2020 of 4.6 percent.***100*** Another analysis shows that U.S. youth smoking rates fell to 6.0 percent by 2019 (thereby surpassing the Healthy People 2020 objective of 16 percent by 386 percent).[101] This pattern, and other analyses, suggest that vaping serves as more of an off-ramp from smoking or as an alternative for adolescents and young adults who would have otherwise initiated smoking. In addition, most adolescent and young adult users of vaping products are infrequent users or experimenters; the minority that use e-cigarettes frequently (defined as 20 to 30 days in the past month) largely comprises those who have already used tobacco. In 2018, only 1 percent of teens who never used tobacco frequently vaped.[102]

79. Furthermore, the most recent data from the U.S. Centers for Disease Control show that vaping among U.S. teens has decreased since 2019. That year, 10.5 percent of middle school students and 27.5 percent of high schoolers used an e-cigarette at least once in the past month. In 2020, 4.7 percent of middle and 19.6

percent high school students reported using e-cigarettes within the past 30 days (current use), according to the CDC. In 2021, 2.8 percent of middle school students and 11.3 percent of high school reported current e-cigarette use.[103] For perspective, 5.4 percent of 12th graders vape daily (while 6.9 percent use marijuana daily and 16.8 percent report binge drinking (more than five drinks in a row in the last two weeks.))[104]

80. The situation is similar in the UK, where the evidence shows that "[r]egular use of electronic cigarettes amongst children and young people is rare and is confined almost entirely to those who currently or have previously smoked." A 2021 factsheet by UK ASH on the use of e-cigarettes among young people in Great Britain found that "while some people, particularly those who have tried smoking, experiment with e-cigarettes, regular use remains low." ASH also found that: "[u]se of e-cigarettes remains largely confined to current or former smokers. The overwhelming majority, 95.4% in total, of 11-17 year old never smokers have either never used an e-cigarette (84.3%) or are not aware of them (10.7%)" and "[o]f 11-17 year old never smokers, 3.3% have tried e-cigarettes once or twice, 0.5% use them less than weekly, and 0.2% use e-cigarettes more than once a week. Only 1 single never smoker reported vaping daily, and only 0.3% were previous users of e-cigarettes."[105]

81. It should also be noted that the gateway claim itself is ambiguous, in part because commentators use the term "gateway" in various ways. Sometimes “gateway” simply refers to a sequence (action B came after action A); and at other times it refers to a predictive, causal statement (a person engaged in action B because he first engaged in A). It is the latter that policymakers should care about – that is, but for the use of A would B have happened – but causality is very hard to prove by examining observational data.

82. After all, it is possible that action B would have happened independent of behavior A. For example, a teen with a high tendency toward risk-taking behavior, such as alcohol and marijuana use, or one who is subject to peer and familial influences that promote risk-seeking behavior, would be prone to try or use both e-cigarettes and cigarettes independently of each other. This phenomenon is known as “the common liability theory” of associated behaviors.[106] Such a teen, therefore, might well have smoked, whether or not he first vaped, based on shared innate and experiential factors. *A* number of large studies confirm this “third-factor” dynamic.[107] It would be wrong to infer, therefore, that someone who vaped and then went on to smoke did so because vaping was a causal “gateway” to smoking, when personal, peer and family influences that correlate with a higher propensity to vape are similar to the same factors that correlate with a higher propensity to smoke.

83. This common liability theory is supported by data from Wave 1 (2013-2014) of the Population Assessment of Tobacco and Health (PATH) by Nicksic and others. The researchers found that general interest in vaping, peer influences, social norms, desirable attributes, and goal-directed reasons influence e-cigarette uptake in both teens and adults.[108] These same factors are influential in prompting adolescent smoking initiation. Researchers also enquired about flavors in the context of “reasons to use” e-cigarettes and found that “*It comes in flavors I like*” lagged sixth in an array of reasons,

including the fact that they "might be less harmful to people around me," "they do not smell," and others.

84. Likewise, researchers in a 2020 study published in *Nicotine & Tobacco Research*, examined respondents to the 2015–2016 waves of US Monitoring the Future survey[109] using propensity score methods to robustly adjust for shared risks in estimating the relationship between e-cigarette use and conventional smoking. Among those 14 shared risk factors were: disciplinary problems, current alcohol or marijuana, or lifetime illicit drug consumption, and the highest level of education completed by the father. After accounting for the propensity for using e-cigarettes based on these 14 risk factors, both lifetime and current e-cigarette use did not significantly increase the risk of current conventional cigarette smoking. The authors state that these findings do not support "the concerns that e-cigarettes act as a 'gateway' to conventional cigarette smoking…."

85. These data indicate that e-cigarettes do not exert a causal effect on concurrent conventional smoking among adolescents and young adults. Such findings also parallel already well-established predictors of progression from the first few puffs to daily smoking. As reviewed by Wellman and colleagues in the *American Journal of Prevention*, these factors include male sex, lower socio-economic status, poor academic performance, sensation-seeking or rebelliousness, intention to smoke in the future, receptivity to tobacco promotion efforts, susceptibility to smoking, family members' smoking, and having friends who smoke. Higher self-esteem and high parental monitoring/supervision of the child appeared to protect against smoking onset.[110]

86. Consistent with these data, one research team confirmed that associations between adolescent e-cigarette use and subsequent smoking are more likely to arise from common risk factors in a 2020 paper entitled, "The Relationship Between Electronic Cigarette Use and Conventional Cigarette Smoking Is Largely Attributable to Shared Risk Factor."[111] Examining cross-sectional data from 8th and 10th graders drawn from the 2015–2016 waves of U.S. Monitoring the Future survey, the authors inferred that "the apparent relationship between e-cigarette use and *current* conventional smoking is fully explained by shared risk factors, thus failing to support claims that e-cigarettes have a causal effect on concurrent conventional smoking among youth." Along those lines, another article entitled, "High School Seniors Who Used E-Cigarettes May Have Otherwise Been Cigarette Smokers: Evidence from Monitoring the Future (United States, 2009–2018),"[112] found that among non-smoking youth, vaping is largely concentrated among those who would have likely smoked prior to the introduction of e-cigarettes. Furthermore, and strikingly, the introduction of e-cigarettes coincided with an acceleration in the decline in youth smoking rates, the report revealed.

87. Reviewing the most recent (2020) longitudinal data from the U.S. Population Assessment of Tobacco and Health (PATH), a team of epidemiologists integrated data over six years, expressed in waves (wave 1: 2013–2014; wave 2: 2014–2015; wave 3: 2015–2016; wave 4: 2016–2017; wave 4.5: 2017–2018; and wave 5: 2018–2019).[113] Notably, this study, which appeared in *Nicotine and Tobacco Research* in December 2021 included an unprecedented set of dependent variables (e.g., the adolescents' exposure to tobacco users (family members who

use tobacco, secondhand smoke exposure, friends who use tobacco); cigarette smoking susceptibility; and behavioral risk factors, specifically including respondents' previous use of other tobacco products, alcohol, and marijuana as measures of adolescents' proclivity for use of psychoactive substances.) The study aimed to determine whether a more substantial set of covariates affected the finding of a statistically significant association between vaping at baseline and subsequent smoking. The answer was 'yes': adjusting for a full set of confounders weakened substantially the association of ever e-cigarette use with subsequent smoking and even became non-significant in some waves, using both past 12-month and past 30-day smoking as outcomes. In brief, the researchers report having found "no direct association between ever vaping and subsequent cigarette smoking among adolescents."

88. A recent study published in *Addiction*[114] which was carried out by researchers from the Department of Behavioural Science and Health, University College London, UK, assesses how changes in the prevalence of e-cigarette use among young adults have been associated with changes in the uptake of smoking in England between 2007 and 2018. The authors use a time series analysis. The researchers found that there was evidence for no association between the prevalence of e-cigarette use and ever-regular smoking among those aged 16–24.

VIII. IMPLICATIONS FOR PUBLIC HEALTH POLICY

89. Adverse health consequences of combustible tobacco products are significant. The WHO estimates that there are 1.3 billion tobacco users worldwide and that tobacco kills more than 8 million people each year.

90. The products of combustion of tobacco, such as tar and other toxins and gases, are the overwhelming source of carcinogens and the cause of hypertension, lung disease, and cardiovascular pathology associated with smoking. In general, nicotine products that do not involve combustion, including e-cigarettes and HNB products, are less hazardous than those that burn tobacco leaves.

91. In my opinion, current smokers must have access to and be properly informed about safer options. This imperative is aligned with the WHO FCTC, which includes tobacco harm reduction within its principles.

92. In their campaigns against e-cigarettes, many health agencies and advocates breach two fundamental tenets of public-health practice: dispassionate and nuanced analysis of risk and honest communication about that risk to the public. Opponents of vaping often define the problem solely as a matter of teen vaping while abdicating their responsibility to address the problem of adult smoking. Youth should not vape, nor should adults smoke. Both imperatives need to be taken into account and trade-offs made. Unfortunately, a vast swath of the tobacco-control community seem to forget that the purview of public health is the nation's entire population of vulnerable people, not just youth, and particularly groups that smoke at disproportionately high rates, including people suffering mental illness, working-class men and women, indigenous people and LGBT+ adults.

93. The ultimate loss of perspective, jarring in its significance to anyone who looks beyond the vaping debate, is that regulation which restricts access or awareness of safer alternatives is liable to have an adverse impact on public health by

perpetuating the use of more hazardous combustible cigarettes. In an essay published in September 2021[115], fifteen past presidents of a leading professional academic society in the field of tobacco control, the Society for Research on Nicotine and Tobacco (SRNT), concluded: "While evidence suggests that vaping is currently increasing smoking cessation, the impact could be much larger if the public health community paid serious attention to vaping's potential to help adult smokers, smokers received accurate information about the relative risks of vaping and smoking, and policies were designed with the potential effects on smokers in mind. That is not happening."

94. Public health policy should be directed to educating smokers about the comparative risks of different tobacco and nicotine products and facilitating a switch to less risky substitutes, and not be such as to discourage or make that switch more difficult.

95. However, national and local governments are proposing and implementing a growing number of restrictive measures on non-combustibles. Product bans, too, have been implemented. Other restrictions include prohibiting flavors other than tobacco, restricting nicotine content, applying the same restrictions for tobacco products to non-combustibles, such as tobacco style large graphic health warnings, standardized packaging of products, retail display bans, and higher taxes. In my opinion, these types of restrictive measures are ill-advised.

96. There is no doubt that these measures will cause many smokers to refrain from switching to safer alternatives, to lure those who have already switched back to smoking or to patronize illicit markets. Banning the sale of non-combustibles outright virtually guarantees that smokers will continue smoking. It also puts teens — the very stimulus for the ban — at increased risk for smoking.

97. As noted above, when flavored vapes are no longer available, many nicotine users won't just quit. Some will use cigarettes. Others will turn to the unregulated black market to continue buying flavored e-cigarettes, for which vapers have a strong preference.

98. Similarly restricting the nicotine content of alternative products to low levels would likely discourage switching and increase relapse. As noted above, research indicates that regulations that unduly restrict the nicotine level in e-cigarettes to levels that smokers find unsatisfactory undermine the potential for smokers to switch away from smoking.

99. Regulating non-combustibles in the same way as combustible products, including requiring the same style of warnings, requiring the same standardized packaging as tobacco products, and banning product displays, conveys the message that these products pose the same health risks as combustible tobacco products. As noted above, existing misperceptions are likely preventing some smokers from switching to non-combustibles. Recognized public health experts Lyn Kozlowski and David Sweanor state that, "[t]he error of presenting products with no meaningful risk reduction as if they were safer cannot be redressed by committing the equally life-threatening error of presenting products with large risk reductions as if they are not safer or by concealing this information." Omitting health-relevant information for consumers, the duo states, "effectively blindfolds them and impairs their making informed personal choices."[116]

100. Policymakers should also make non-combustibles more accessible to smokers by eschewing hefty taxes. While high cigarette taxation can be justified by the adverse health effects of smoking, such rationale does not apply to safer alternatives. Imposing significant taxes on non-combustible products would make them less accessible as alternatives to smoking and will predictably perpetuate the demand for combustibles.

101. As for concerns regarding youth, everyone agrees they should not vape. However, as discussed above, an extremely small percentage of teenagers use e-cigarettes regularly, and one of the biggest concerns — namely, that teen vaping leads to teen smoking through a so-called gateway effect — is unsubstantiated. There is also evidence that vaping is diverting some youth away from more dangerous smoking.

102. Policymakers should require reliable, informative labeling and safe manufacturing standards for e-cigarettes. They should also allay concerns about potential gateway use and youth addiction to nicotine by banning the marketing and sale of e-cigarettes to minors. However, they should not be heavy-handed in restricting marketing and sales to adults. Instead, promoting electronic cigarettes to smokers should be a public health priority.

103. Given the direct medical costs of smoking as well as the productivity losses from premature deaths, persuading more smokers to switch would result in significant cost savings — as well as millions of lives saved each year. As noted by David Abrams of the NYU College of Global Public Health "*If we lose this opportunity, I think we will have blown the single biggest public health opportunity we've ever had in 120 years to get rid of cigarettes and replace them with a much safer form of nicotine for everybody.*"[117]

IX. CONCLUSION

104. The purview of public health is the nation's entire population. That includes adult smokers, particularly those who smoke at disproportionately high rates, namely, people suffering mental illness, working-class men and women, those who live in rural areas, indigenous people, and LGBT+ adults. Governments and regulators must not allow the intense focus on teen use – warranted though it is – to divert all attention from the benefits of vaping for adult smokers, millions of who die each year from smoking-related diseases.

105. Intrinsic to the controversy in relation to non-combustibles is the fact that the benefits of these products to smokers are not widely appreciated. What's more, studies purporting to have identified vaping-related harms often exaggerate those alleged negative effects. Researchers cannot conduct an optimal analysis of the risks and benefits of vaping to the population as a whole – a public health imperative –unless they take into account the significant advantages of non-combustibles to smokers. Finally, when the known realities are considered, it becomes clear that it is irrational to impose bans or overly restrictive regulations on non-combustibles which will inhibit the tobacco harm reduction potential of these products for smokers.

106. A number of harmful unintended consequences will likely result from bans and overly restrictive regulation. An outright ban on non-combustibles or overly restrictive regulation (including overly restrictive caps on nicotine strength, flavor

bans, the application of restrictive tobacco product regulation, or taxation at the high rates that apply to combustible cigarettes), will almost surely disadvantage adults who have already switched or those who could do so in the future, as well as teens who would otherwise smoke.

107. Regrettably, the vaping issue has been cast as a contest between the health of teens and the health of smokers. But Governments should and can seek to protect both. They can protect teens through more robust barriers to access and prohibiting marketing directed at teens. At the same time, Governments can save smokers' lives and combat the leading cause of preventable death in the world by preserving adult smokers' access to reduced-risk alternatives.

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Sally L. Satel, M.D.
Curriculum Vitae

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Birth place:	New York, NY
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Academic Appointments, Hospital Appointments, and Other Work Experience

2019 - Present	Vising Professor of Psychiatry, Department of Psychiatry, Columbia University Irving Medical Center, Department of Behavioral Health Services and Policy Research
2018 - Present	Clinical Consultant, Ironton-Lawrence Community Action Organization, Addiction treatment
2010 - Present	Psychiatric consultant, Partners in Drug Abuse Rehab and Counseling (PIDARC)
2002 - Present	resident scholar, American Enterprise Institute
2000 - Present	Resident Scholar, American Enterprise Institute Project
1995 - Present	Lecturer, Yale University School of Medicine
1997 - 2009	Staff Psychiatrist, Oasis Clinic
1996 - 1997	Professional Staff, U.S. Senate Veterans' Affairs Committee
1995 - 1996	Staff Psychiatrist, District of Columbia Superior Court Pretrial Program
1995 - 1996	Consultant to the U.S. Senate Special Committee on Aging
1994 - 1996	Visiting Research Scientist, University of Pennsylvania School of Medicine
1988 – 1995	Assistant Professor of Psychiatry, Yale University School of Medicine

1993 – 1994	Robert Wood Johnson Health Policy Fellow, Office of Senator Nancy L. Kassebaum (R-KS)
1990 - 1993	Member medical school admissions committee
1988 – 1993	Staff psychiatrist, West Haven VA Medical Center, Yale University School of Medicine

Education

8/1982-6/1984	M.D., Warren Alpert Medical School of Brown University, Boston, MA
7/1977-6/1982	M.S. in Anatomy, University of Chicago
8/1973-6/1977	B.S. in Biology, Cornell University

Training

1985 – 1988	Resident in Psychiatry, Yale University School of Medicine
1984 – 1985	Intern, Flexible Internship, Hospital of St. Raphael, Yale University School of Medicine

Board Certification

1997	Board of Psychiatry and Neurology

Honors and Awards

1993 - 1994	Laughlin Fellowship (American College of Psychiatrists) for outstanding resident
1988	Robert Wood Johnson Health Policy Fellowship

Academic Services

2018 - 2021	Member, National Advisory Council of the Substance Abuse and Mental Health Services Administration
2002 – 2006	Member, Advisory Council, Center for Mental Health Services
2003 – 2003	Member, Advisory Council, Center for Mental Health Services
1996 – 2003	Member, Editorial Board, Psychiatric Services

Fellowship and Grant Support

1999 – 2000	Robert Wood Johnson Foundation President's Grant Co-Investigator; wrote a paper on Drugs in courts $50,000.00

Publications

Peer-Reviewed Research Publications in Print or other Media

1. **Satel, S. L**.*, & Lilienfeld, S.O. (2016). If addiction is not best conceptualized a brain disease, then what kind of disease is it? *Neuroethics* Nov 17.

2. **Satel, S**.*, & Cronin D.C. (2015). Time to test incentives to increase organ donation (Commentary) *JAMA Intern Med*. 175(8):1329-30.

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8. **Satel, S**.* (2010). The physician's voice is only one of many. *American Journal of Transplantation,* July 15.

9. Matas, A.J., Hippen, B., & **Satel, S**. (2008). In defense of a regulated system of compensation for living donation. *Current Opinion in Organ Transplantation, 13*(4): 379-85.

10. **Satel, S. L**.* (2007). 9/11: Mental health in the wake of terrorist attacks. *Psychiatric Services, 58*(February):276-77.

11. **Satel, S. L**.*, & Hippen, B. E. (2007). When altruism is not enough: The worsening organ shortage and what it means for the elderly. *The Elder Law Journal, 15*(1):101-152.

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14. **Satel, S**.* (2005). Posttraumatic Stress Disorder: Issues and Controversies. *Psychiatric Services, 56*:758-759.

15. **Satel, S**.*, & Klick, J. (2005). The Institute of Medicine report: too quick to diagnose bias. *Perspectives in Biology and Medicine, 48*(1 Suppl): S15-25.

16. **Satel, S. L**.* (2003). A war of nerves: Soldiers and psychiatrists in the twentieth century. *Psychiatric Services, 54*(3): 405-406.

17. **Satel, S. L**.* (2003) The mental health crisis that wasn't. *Psychiatric Services, 54*(12):1571.

18. **Satel, S. L**.* (2001). Commentary: Who needs trauma initiatives? *Psychiatric Services, 52*(6):815.

19. **Satel, S**.* (2000). Addiction is a choice. *Psychiatric Services, 52*(4): 539-540.

20. Caulkins, J., & **Satel, S**. (1999). Methadone patients should not be allowed to persist in cocaine use. *FAS Drug Policy Analysis Bulletin, 6*(January).

21. **Satel, S. L**.*, & Aeschbach, E. (1999). The Swiss heroin trials. Scientifically sound? *Journal of Substance Abuse Treatment, 17*(4):331-5.

22. **Satel, S. L**.* (1999). What should we expect from drug abusers? *Psychiatric Services, 50*(7):861.

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3. **Satel, S**.* (2019, February 13). Vaping Is Harm Reduction: The surgeon general is right on opioids, but wrong on tobacco. *Wall Street Journal*.

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7. **Satel, S**.*, & Kertesz, S. (2018, August 17). Oregon overshoots on opioids. *Wall Street Journal*.

8. **Satel, S**.* (2018, August 8). 'Dopesick' and 'The Addiction Solution' review: Examining an epidemic. *Wall Street Journal*.

9. **Satel, S**.* (2018, May 15). Vapin' in the boys' room. *Wall Street Journal*.

10. Rich, J., & **Satel, S**.* (2018, May 8). Access to maintenance medications for opioid addiction is expanding. Prisons need to get on board. *Slate*.

11. **Satel, S**.* (2018, April 11). Why the panic over JUUL and teen vaping may have deadly results. *Forbes*.

12. **Satel, S**.*, & Kertesz, S. (2018, March 30). Pill limits are not a smart way to fight the opioid crisis. *Slate*.

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34. **Satel, S**.* (2017, February 21). Right to try, right to buy, right to test. *Washington Post*.

35. **Satel, S**.* (2017, February 9). Her damaged brain forgot new experiences but she still improved on the viola. *Washington Post*.

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37. **Satel, S**.* (2017, January 13). How to treat an opioid epidemic. *Wall Street Journal*.

38. **Satel, S**.* (2016, December 31). The year in e-cigarettes: the good, the bad, and some reasons for optimism. *Forbes*.

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40. **Satel, S**.*, & Sweanor, D. (2016, December 19). Dear surgeon general and public health agencies, anti-vaping polices are bad for public health. *RealClearHealth*.

41. **Satel, S**.* (2016, December 8). Big tobacco is giving away money: Researchers should take it. *Forbes*.

42. **Satel, S**.* (2016, December 7). Shortcuts to addiction. *Wall Street Journal*.

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45. **Satel, S***. (2016, November 15). You've heard of trump steaks, now trump kidneys. *Forbes*.

46. **Satel, S**.*, & Bates, C. (2016, November 8). Could changes to a global tobacco treaty harm health? *Slate*.

47. **Satel, S**.* (2016, October 17). California ballot choices: to protect porn stars but not smokers? *Forbes*.

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49. **Satel, S**.* (2016, September 26). Shameless campaign for tobacco-free kids tries to censor researchers. *Forbes*.

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Amicus Briefs

1. Heyman, G. M., Morse, S. J., Lilienfeld, S. O., **Satel, S. L**., *Commonwealth v. J*

Analysis of Risk Beliefs and Usage of E-Cigarettes and other Potentially Reduced Risk Nicotine Products in Europe

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I. INTRODUCTION

1. I am the University Distinguished Professor of Law, Economics, and Management at Vanderbilt University. I hold a bachelor's degree in Economics, two master's degrees, and a Ph.D. in economics, all from Harvard University. I have published almost 400 articles and over 30 books dealing primarily with health and safety risks, and I have been ranked among the top 25 economists in the world based on citations in economics journals. I worked extensively with the U.S. Environmental Protection Agency ("EPA") on a continuous basis from 1983 to 2012, where much of my work was focused on the development of guidelines for hazard warnings for dangerous pesticides and chemicals.

2. In addition to my extensive work for EPA, I have consulted for several other governmental entities on a variety of issues, including the U.S. Department of Transportation, the U.S. Department of Labor, the U.S. Department of Justice, the U.S. General Accounting Office, the U.S. Department of Health and Human Services, the U.S. Office of Management and Budget, and the National Oceanic and Atmospheric Administration. I have also taught courses about risk, uncertainty, risk analysis, and hazard warnings to hundreds of Food and Drug Administration officials, congressional staff, and federal and state judges. I served as the Associate Reporter on The American Law Institute Study on Enterprise Responsibility for Personal Injury and co-wrote the chapter on Product Defects and Warnings. I have also testified before the U.S. Congress on nine occasions as an expert in economics and risk analysis. This testimony addressed such topics as, for example, alcoholic beverage warnings.

3. Apart from my academic and governmental work, I have consulted on matters such as risk perception, hazard warnings design, and safety devices for large companies,

including Bic, DuPont, Becton Dickinson, R.J. Reynolds, Bristol-Meyers Squibb, Anheuser-Busch, Black & Decker, and Medline Industries. I have submitted several expert reports on behalf of British American Tobacco group companies in relation to proposed tobacco regulation, including the introduction of graphic health warning requirements and legal challenges to such regulation. I have also served as a consultant/expert witness for the United States Department of Justice in a variety of cases. These include an analysis of natural resource damages issues in connection with the Exxon Valdez oil spill. I have also testified on behalf of the Province of Quebec on risks and warnings for video lottery terminals.

4. I am a founding editor of two journals: the Journal of Risk and Uncertainty, which publishes peer reviewed articles on issues relating to risk perception and analysis; and Foundations and Trends: Microeconomics. I am currently on the board of several other academic journals, including Regulation; Journal of Law, Economics and Policy; Journal of Tort Law; Contemporary Economic Policy; Regulation and Governance; Managerial and Decision Economics; Journal of Risk and Insurance; Journal of Benefit-Cost Analysis; and The Geneva Risk and Insurance Review. I have also held editorial positions with such journals as American Economic Review, which is the official journal of the American Economic Association; Review of Economics and Statistics, a journal specializing in quantitative applied economics and based at Harvard University; Journal of Environmental Economics & Management; Public Policy; International Review of Law and Economics; and Journal of Regulatory Economics. I have served as a peer reviewer for dozens of other publications and for government agencies in countries throughout the world.

5. I have won several awards for my books and articles. These include the "Article of the Year" award from the Western Economic Association for an article on the valuation of life; the "Article of the Year" award from the Royal Economic Society, an international economic society based in England, for an analysis of how ambiguous risk information influences decision-making; the "Article of the Year" award from the American Risk and Insurance Association for an article on automobile insurance regulation; and two "Article of the Year" awards from the Society for Benefit-Cost Analysis. I am also a five-time winner of the Kulp-Wright Award for "Book of the Year," given out by the American Risk and Insurance Association. Other recent professional awards include being named an Honorary Member of the Academy of Economics and Finance; winning the University of Chicago Law School's Ronald H. Coase Prize for an article on risk perception; and winning the 2019 Vanderbilt University Earl Sutherland prize, which is the school's most prestigious university-wide award for scholarly accomplishment.

6. Much of my scholarly research and writing has focused on issues of risk and health relating to smoking. My work on risk analysis, risk perception, consumer behavior, and regulation as it relates to smoking has included extensive research into the history of the tobacco industry and the related public health discussions, as well as current events as they pertain to these issues. These articles have been widely disseminated and subject to peer review.

7. I have also written two books exclusively related to smoking. The first, *Smoking: Making the Risky Decision* (Oxford University Press, 1992) is about smoking and smoking risks, and analyzes how the available information about smoking has changed over time, how people have assessed the risks of smoking, and how those risk perceptions

affect smoking behavior. The book also explains how changes in the price of cigarettes affect cigarette consumption. The second book, *Smoke-Filled Rooms: A Postmortem on the Tobacco Deal* (University of Chicago Press, 2002), includes chapters on risk perceptions and addiction, youth smoking, environmental tobacco smoke, the promotion of potentially safer cigarettes, the settlement of the U.S. state litigation against the tobacco industry, the U.S. Master Settlement Agreement, and the financial costs of smoking. Both books were subject to peer review. A full copy of my Curriculum Vitae is available at https://law.vanderbilt.edu/phd/faculty/w-kip-viscusi/ViscusiCV.pdf.

8. I have been asked by British American Tobacco to provide a report that examines the evidence on e-cigarette risk beliefs and the relationship of these beliefs to e-cigarette usage, as well as presenting an analysis of data from a new survey conducted in selected European markets. I assisted in the design of this survey, which examines the e-cigarette risk beliefs of a sample of smokers, dual users, and exclusive e-cigarette users, as well as their risk beliefs for heated tobacco products and oral nicotine pouch products. In this report, I present an analysis of the risk beliefs regarding these different products and the impact of those beliefs on product usage. I also consider the implications of current risk beliefs for informed consumer choice and the potential public health benefits that these alternative potentially reduced risk products offer. Drawing on the implications of these empirical results, I propose several policy recommendations for Governments/regulators.

II. EXECUTIVE SUMMARY

9. Numerous studies and comprehensive reviews by public health authorities have stated that e-cigarettes are less harmful than conventional tobacco cigarettes. Nevertheless,

surveys in the UK and the US report that many people believe that e-cigarettes are as harmful or more harmful than cigarettes. Failure to understand the lower estimated risks associated with e-cigarettes will discourage e-cigarette use.

10. The trend in survey reports indicating beliefs that e-cigarettes are as harmful or more harmful than cigarettes is not favorable. The percentage of the population who regard e-cigarettes as being as harmful or more harmful than cigarettes has been increasing over time, particularly in recent survey waves.

11. This report analyzes data from a survey in 2020 of adults who currently smoke cigarettes exclusively, currently smoke cigarettes and use e-cigarettes, or use e-cigarettes but do not currently smoke cigarettes. The countries included in the sample are the United Kingdom, Belgium, Denmark, the Netherlands, France, Germany, and Italy.

12. The focus of the survey was on respondents' perceptions of the estimated harm of e-cigarettes compared to conventional cigarettes, and their usage of e-cigarettes. In addition, the survey also obtained information on other potentially reduced risk alternatives to cigarettes, specifically heated tobacco products,[1] and oral nicotine pouches.[2]

[1] Heated tobacco products (also known as 'heat-not-burn' tobacco products) are devices that heat tobacco to generate a nicotine-containing aerosol which the user inhales. Because the tobacco is only heated and not burned, the resulting aerosol can potentially contain substantially lower levels of the toxicants found in the smoke produced when tobacco is burned. In a review of the available evidence carried out for Public Health England in 2018, the authors, while noting the need for further research, concluded that "[t]*he available evidence suggests that heated tobacco products may be considerably less harmful than tobacco cigarettes*." and that "[c]*ompared with cigarettes, heated tobacco products are likely to expose users and bystanders to lower levels of particulate matter and harmful and potentially harmful compounds (HPHC). The extent of the reduction found varies between studies*." McNeill A, Brose LS, Calder R, Bauld L & Robson D (2018). Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England.

[2] Oral nicotine pouches are pre-portioned porous pouches containing nicotine (but no tobacco). The user puts a pouch between the upper lip and gum and leaves it there while the nicotine and taste are released. No combustion is involved. As oral nicotine pouches do not contain any tobacco, they contain far fewer and lower levels of toxicants than cigarettes and other tobacco products like snus.

13. Beliefs that e-cigarettes are less harmful than tobacco burning cigarettes are positively correlated with e-cigarette use. Those who consider e-cigarettes to be less harmful than cigarettes are 33% more likely to currently use e-cigarettes. For nonsmokers who formerly smoked, those who consider e-cigarettes to be less harmful than cigarettes are 9% more likely to currently use e-cigarettes and not smoke conventional cigarettes.

14. Respondents in the UK, a market that has taken a more progressive approach to the regulation of e-cigarettes than many of the other European countries analyzed in this study, are significantly more likely to believe that e-cigarettes are less harmful than respondents in any other country other than Italy, for which the difference in the levels of beliefs compared to the UK is not statistically significant.

15. Controlling for personal characteristics and the respondents' country, e-cigarette use is negatively related to being a cigarette smoker, with e-cigarette users being 48% less likely to also be a current smoker.

16. Not knowing enough about e-cigarettes and not believing that they are less harmful are the two principal reasons that people cite for not using e-cigarettes, while beliefs that they will help cut down or stop smoking are the main reasons given for using e-cigarettes.

17. A substantial number of the survey respondents were unfamiliar with heated tobacco products and oral nicotine pouches, with 35% of respondents stating that they had not heard of a heated tobacco product and 53% of respondents stating that they had not heard of oral nicotine pouches.

18. Beliefs that heated tobacco products and nicotine pouches are less harmful than cigarettes are positively correlated with usage of these products. Respondents who perceive heated tobacco products as being less harmful than cigarettes are 15% more likely to currently

use heated tobacco products, while the comparable increase in the use of oral nicotine pouches for those who perceive them as being less harmful is 4%.

19. The use of heated tobacco products and oral nicotine pouches is also negatively related to being a current smoker. Users of heated tobacco are 4% less likely to also be a current smoker, and users of oral nicotine pouches are 9% less likely to also be a current smoker.

20. Substantial opportunities remain for more effective risk communication efforts. The current failure by consumers to appreciate the estimated lower risk of these alternative products compared to cigarettes is a major shortfall of consumer knowledge. These beliefs in turn play an instrumental role in consumer decisions regarding the use of these products.

21. Recommended policy changes include both a more vigorous role for informational initiatives by governments as well as framing warnings information so that they facilitate informed consumer choices. Reducing the restrictions that manufacturers face in communicating the comparative estimated risks of these products would also facilitate efforts to inform consumers about the product risks.

III. THE ESTIMATED RISKS OF E-CIGARETTES

22. A principal driver of interest in e-cigarettes (EC) is their estimated risk levels compared to conventional cigarettes that burn tobacco. Because e-cigarettes have been available for a relatively short time compared to cigarettes and other traditional tobacco products, there are no epidemiological studies that have assessed their possible long-term health consequences. There is, however, a substantial literature that has analyzed the chemical composition of e-cigarette vapors and assessed the possible short-term health effects.

The general consensus is that e-cigarettes are estimated to be much less risky than conventional cigarettes.

23. Public Health England has commissioned reviews of the literature in 2015[3] and 2018,[4] each of which provided an extensive assessment of the literature. The 2015 report provided an update of Public Health England's earlier reports on e-cigarettes in the light of new evidence, stating (p. 12): "It has been previously estimated that EC are around 95% safer than smoking. This appears to remain a reasonable estimate." Public Health England (2018, p. 150) reiterated the principal conclusion of the 2015 report: "Since the 2015 Public Health England report, the Royal College of Physicians (RCP) has also reviewed evidence on the safety of EC and concluded that they were 'unlikely to exceed 5% of the harm from smoking to tobacco.'" With respect to the cancer risks posed by e-cigarettes, Public Health England (2018, p. 157) report concluded: "In summary, a study of cancer potencies of EC emissions suggested that these are largely less than 0.4% of smoking." The Public Health England (2018, p. 162) report similarly noted that there was no evidence of significant health risks from passive vaping.

24. The 2018 Public Health England report also included a discussion of what is known at this point about the risks posed by heated tobacco products. While noting that the current evidence for heated tobacco products was limited, the report concluded that compared to conventional cigarettes, heated tobacco products are likely to expose users and bystanders to lower levels of particulate matter and harmful compounds, but pose more risk than e-cigarettes (p. 23). Their overall assessment (p. 24) is that heated tobacco products

[3] Ann McNeill, et al. Evidence Review of E-Cigarettes and Heated Tobacco Products 2015: A Report Commissioned by Public Health England. London: Public Health England, 2015.
[4] Ann McNeill, et al., Evidence Review of E-Cigarettes and Heated Tobacco Products 2018: A Report Commissioned by Public Health England. London: Public Health England, 2018.

"…may be considerably less harmful than tobacco cigarettes and more harmful than e-cigarettes."

25. The 2020 Public Health England evidence update[5] included some cautionary information regarding the absolute risk of e-cigarettes along with the lower comparative risk message from its previous reports (p. 27), noting that "vaping regulated nicotine products has a small fraction of the risks of smoking, but this does not mean it is 'safe'."

26. The US National Academies of Sciences, Engineering, and Medicine (NASEM) undertook a large-scale systematic review of the scientific literature for the US Food and Drug Administration in 2018.[6] While noting the need for studies of the long-run effects of e-cigarettes, the report concludes (p.1) that the current evidence, based on laboratory tests of e-cigarette ingredients, in vitro toxicological tests, and short-term human studies, suggests that e-cigarettes are likely to be far less harmful than combustible tobacco cigarettes. The report also concluded (p. 11): "The evidence about harm reduction suggests that across a range of studies and outcomes, e-cigarettes pose less risk to an individual than combustible tobacco cigarettes."

27. Other prominent studies have reached similar conclusions. Farsalinos and Polosa (2014) also undertook a systematic review of the literature and concluded that the currently available evidence indicates that electronic cigarettes are by far a less harmful alternative to smoking and significant health benefits are expected in smokers who switch from tobacco to electronic cigarettes.[7]

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[5] A. McNeill, L.S. Brose, R. Calder, L. Bauld, and D. Robson. Vaping in England: An Evidence update Including Mental Health and Pregnancy March 2020: A Report Commissioned by Public Health England. London: Public Health England, 2020

[6] National Academies of Sciences, Engineering, and Medicine. 2018. Public Health Consequences of E-Cigarettes. Washington, D.C.: National Academies Press.

[7] K. E. Farsalinos, and R. Polosa. 2014. "Safety Evaluation and Risk Assessment of Electronic Cigarettes as Tobacco Substitutes: A Systematic Review," *Therapeutic Advances in Drug Safety*, 5(2), 67-86.

28. A more recent study by Stephens (2018) found that the cancer potencies of e-cigarettes were less than 1% of tobacco smoke.[8] Heat-not-burn devices were found to have an order of magnitude lower level of potency than tobacco cigarettes but had a higher level of potency than e- cigarettes.

29. Estimates of the health benefits that may result by switching from conventional tobacco cigarettes to e-cigarettes are substantial. Abrams et al. (2018, p. 205) provided the following estimates for the United States smoking population: "Replacement of most cigarette use by e-cigarette use over a 10-year period yields up to 6.6 million fewer premature deaths with 86.7 million fewer life years lost."[9]

30. Recently, the UK Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) concluded that the current evidence indicates that electronic cigarettes are substantially reduced risk compared with combustible cigarettes. COT, which is made up of independent experts, was commissioned by the UK Department of Health and Social Care and Public Health England to review the potential toxicological risks from electronic cigarettes.[10] The review concluded that, although the magnitude of the decrease will depend on the effect in question, the relative risk of adverse health effects would be expected to be substantially lower from e-cigarettes for smokers who completely switch to e-cigarettes, or if e-cigarettes are taken up instead of combustible cigarettes.[11]

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[8] William E. Stephens, "Comparing the Cancer Potencies of Emissions from Vapourised Nicotine Products Including E-Cigarettes with Those of Tobacco Smoke," *Tobacco Control,* Vol. 27, 2018, pp. 10-17.
[9] David B. Abrams, et al. 2018. "Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine Use to Rapidly Save Lives," *Annual Review of Public Health*, Vol. 39, pp. 193-213.
[10] The review included electronic nicotine delivery systems and devices that use an e-liquid that does not contain any nicotine, collectively abbreviated as E(N)NDS
[11] The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment., *Statement on the potential toxicological risks from electronic nicotine (and non-nicotine) delivery systems (E(N)NDS – e-cigarettes)* July 2020 - A report commissioned by the Department of Health and Social Care and Public Health England.

IV. PREVIOUS STUDIES OF THE PERCEPTION OF E-CIGARETTE RISKS

31. There has been an extensive analysis of the perceived harm of e-cigarettes based on surveys of beliefs in the UK and the US. These studies have framed this assessment on a comparative basis using tobacco-burning cigarettes as the reference point. The wording used has usually been in terms of whether e-cigarettes are less harmful, more harmful, or just as harmful as conventional cigarettes. A couple of studies have framed the question in terms of whether e-cigarettes pose less risk, more risk, or just as much risk as conventional cigarettes. For both survey wordings, a substantial segment of the population either does not know whether e-cigarettes pose less harm or believes that e-cigarettes are either just as harmful or more harmful than conventional cigarettes. There has also been evidence of an increase over time in the fraction of the population who regard e-cigarettes as just as harmful or more harmful than conventional cigarettes. Comparison of the survey results in the different studies is sometimes hindered by the fact that some respondents may not be familiar with e-cigarettes, which would lead to a "don't know" response in many surveys. Such "don't know" responses are quite different than that of informed respondents who are not willing to make a judgment on whether e-cigarettes are less harmful. These "don't know" respondents may be similar to viewing the products as being equally harmful.

E-Cigarette Perceptions in the UK

32. Assessing the degree to which the population regards e-cigarettes as less harmful is potentially important from the standpoint of the number of smokers who might switch to e- cigarettes. In a study in England from 2014 to 2019 that followed the behavior of 300

smokers who were surveyed monthly, Perski et al. (2020)[12] found that declines in the belief among current smokers that e-cigarettes are less harmful than combustible cigarettes were strongly associated with declines in the use of e-cigarettes among current tobacco smokers. For every 1% decrease in the mean prevalence of current tobacco smokers who endorsed the belief that e-cigarettes are less harmful than combustible cigarettes, the mean prevalence of e-cigarette use decreased by 0.48%. The authors state:

> "*The reduction in the proportion of tobacco smokers who perceive e-cigarettes to be less harmful than combustible cigarettes from 2014 to 2019 and the associated reduction in the use of e-cigarettes may reflect smokers' concerns about the uncertainty about the long-term health effects of e-cigarettes. These concerns may have been amplified by frequent media reports focusing on the absolute (as opposed to relative) health risks of e-cigarettes or graphic, highly emotive depictions of e-cigarette explosions or e-cigarette or vaping product use-associated lung injury (EVALI) in the US. In line with Huang and colleagues' call for an increase in the availability of accurate risk information about e-cigarettes in mainstream media, our results highlight the need for an increase in media portrayals and public health campaigns focusing on the reduced health harms by switching from combustible tobacco to e-cigarettes and a reduction in alarmist media coverage of events such as EVALI*.".

33. Some studies of beliefs in the UK also include more than one country in the sample. The summaries below present them in rough chronological order of the survey years. The

[12] Olga Perski, Emma Beard, and Jamie Brown. 2020. "Association between Changes in Harm Perceptions and E-Cigarette Use among Current Tobacco Smokers in England: A Time Series Analysis," *BMC Medicine*, 18:98, pp. 1-10. In this study, each 1% decrease in the belief that e-cigarettes are less harmful is associated with a 0.5% decrease in e-cigarette use.

article by Adkinson et al. (2013) used a sample of current and former smokers from mid-2010 to mid-2011 and found that the percentage of respondents who viewed e-cigarettes as being less harmful than conventional cigarettes was 82% in the UK, 71% in Australia, 66% in the US, and 64% in Canada.[13] The average percentage across these studies was 70%. Most respondents--80%-- indicated that they used e-cigarettes because they were less harmful than conventional cigarettes, 75% said that they did so to reduce their smoking, and 85% said it was to help them quit smoking.

34. Another result from UK samples over two years reported that, excluding "don't know" responses, the percentage of the population who viewed e-cigarettes as less harmful than cigarettes decreased from 86.4% in 2013 to 78.2% in 2014.[14]

35. Public Health England (2015) reported the results of a series of surveys for the UK and Europe, noting that the trend in risk beliefs displayed a disturbing pattern (p. 6): "There has been an overall shift towards the inaccurate perception of e-cigarettes being as harmful as cigarettes over the last year in contrast to the current expert estimate that using e-cigarettes is around 95% safer than smoking." The Internet Cohort Great Britain Surveys reported by Public Health England (2015) covered the years from 2012 to 2014. The percentage who viewed e-cigarettes as less harmful than cigarettes was 67% in 2012, 67% in 2013, and 60% in 2014. The beliefs that the products are equally harmful rose from 9% in 2012 to 11% in 2013 and to 17% in 2014. The percentage who viewed e-cigarettes as more harmful than cigarettes remained at 2% throughout that period, while the "don't know" percentage declined from 23% in 2012 and to 21% in 2013 and 2014.

[13] Sarah E. Adkinson, et al. 2013. "Electronic Nicotine Delivery Systems: International Tobacco Control Four-Country Survey," *Am. J. Prev. Med.,* Vol. 44, No. 3, pp. 207-215.
[14] Leonie S. Brose, et al. 2015. "Perceived Relative Harm of Electronic Cigarettes over Time and Impact on Subsequent Use. A Survey with 1-Year and 2-Year Follow-ups," *Drug and Alcohol Dependence*, Vol. 157, 106-111.

The ASH Smokefree Great Britain Surveys reported by Public Health England (2015) show somewhat different levels of harm beliefs. The percentage who viewed e-cigarettes as less harmful than cigarettes rose from 52% in 2013 to 54% in 2014 and 2015. The equally harmful beliefs rose from 6% in 2013 to 14% in 2014 and 20% in 2015. The percentage who viewed e-cigarettes as more harmful than cigarettes remained low at 1% in 2013 and 2% in 2014 and 2015. There was a decline over time in the "don't know" percentage from 40% in 2013 to 30% in 2014 and 23% in 2015. However, the ASH Smokefree Great Britain Youth Surveys reported a decline in the belief that e-cigarettes are less risky than cigarettes from 74% in 2013 to 66% in 2014 and 67% in 2015, coupled with an almost doubling of the equally-risky beliefs from 12% in 2013 to 21% in 2015.

36. Action on Smoking and Health (ASH 2019) reported survey results among adults in Great Britain who have heard of e-cigarettes.[15] Those who viewed e-cigarettes as equally harmful or more harmful rose from 7% in 2013 to 15% in 2014, and subsequently to 26% in 2019. Among adult smokers, the percent who viewed e-cigarettes as equally harmful or more harmful was 8% in 2013 and 10% in 2014, rising to the much higher value of 22% in 2019.

37. The Public Health England (2020) report by A. McNeill et al. presented survey results for 2019 and compared them with results for an adult sample in 2014 (p. 97). The percentage of respondents who regarded e-cigarettes as less harmful than cigarettes dropped from 45% in 2014 to 34% in 2019. The report stated these misperceptions are particularly common among smokers who do not vape. The response group exhibiting the greatest change was that in which e-cigarettes and conventional tobacco-burning

[16] Action on Smoking and Health (ASH). 2020. "Use of E-Cigarettes (Vapes) among Adults in Great Britain, October 2020."

cigarettes are viewed as being equally harmful, as that fraction rose from 26% in 2014 to 42% in 2019. The remaining categories in 2019 consisted of 14% who viewed e-cigarettes as more harmful than cigarettes and 10% who indicated that they did not know. Similar changes in harm beliefs were also evident for the ASH-Y data for youths, as two-thirds of respondents viewed e-cigarettes as less harmful than cigarettes in 2014 and just over one-half did so in 2019 (p. 53).

38. An article by Wilson, et al. (2019) reported perception of harm results for a longitudinal UK sample interviewed in 2017. Overall, 57% believed that e-cigarettes are less harmful than cigarettes, 22% believed that e-cigarettes and cigarettes are equally harmful, 3% believed that e-cigarettes are more harmful than cigarettes, and 18% indicated that they did not know.

39. Perhaps influenced in part by the e-cigarette, or vaping, product use associated lung injury (EVALI) illnesses in the US, respondents to the 2020 Action on Smoking and Health Survey viewed e-cigarettes even less favorably compared to cigarettes.[16] Particularly striking is that 37% of adults and 34% of smokers regarded e-cigarettes as more harmful than or as harmful as cigarettes. Reporting on the Survey, ASH states: '[t]he proportion of the adult population thinking that e-cigarettes are more or equally harmful as smoking is five times higher than in 2013, increasing from 7% in 2013 to 37% in 2020' and '… in 2020 perceptions have shifted markedly with the highest proportion of people reporting inaccurate misperceptions that e-cigarettes are more harmful than smoking (37%) and the lowest proportion reporting that e-cigarettes are less or a lot less harmful (39%).'

[16] Action on Smoking and Health (ASH). 2020. "Use of E-Cigarettes (Vapes) among Adults in Great Britain, October 2020."

E-Cigarette Perceptions in the US

40. The pattern of harm beliefs in the United States also indicates that a substantial part of the population is not aware of the estimated comparative harm of e-cigarettes and conventional cigarettes. Richardson, et al. (2014) reported that in a 2011 survey of current and former smokers, the percentage distribution of comparative beliefs regarding harms of e-cigarettes was 21% don't know, 65% less harmful, 10% about the same harm, and 3% more harmful.[17] The less harmful belief percentages were lower for snus (12%), chewing tobacco, snuff, and dip (10%), and dissolvables (17%).

41. Results reported by Kiviniemi and Kozlowski (2015) using data from the US Health Information National Trends Survey (HINTS), a population-representative survey of US adults, for 2012-2013 were that 11% viewed e-cigarettes as much less harmful than cigarettes, 40% viewed them as less harmful than cigarettes, 46% viewed them as just as harmful as cigarettes, 1.6% viewed them as more harmful than cigarettes, and 1.2% viewed them to be much more harmful than cigarettes.[18] Combining the as harmful and more harmful groups, 49% believed that e-cigarettes are as harmful as or more harmful than cigarettes.

42. Persoskie, et al. (2019) reported trends of declining beliefs that e-cigarettes are less harmful than cigarettes from 45% in 2012 to 34% in 2017.[19] In wave two of the US National Population Assessment of Tobacco and Health (PATH) Study, 59% of those

[17] Amanda Richardson, et al. 2014. "Prevalence, Harm Perceptions, and Reasons for Using Noncombustible Tobacco Products Among Current and Former Smokers," *Am. J. of Public Health*, Vol. 104, No. 8, pp. 1437-1444.
[18] Marc T. Kiviniemi and Lynn T. Kozlowski. 2015. "Deficiencies in Public Understanding about Tobacco Harm Reduction: Results from a United States National Survey," *Harm Reduction Journal*, Vol. 12, No. 21, pp. 1-7.
[19] Alexander Persoskie, Erin Keely O'Brien, and Karl Poonai. 2019. "Perceived Relative Harm of Using E-Cigarettes Predicts Future Product Switching among U.S. Adult Cigarette and E-Cigarette Dual Users," *Addiction*, Vol. 114, pp. 2197-2205.

who used both e-cigarettes and cigarettes perceive the former as being less harmful, 35% considered the harms to be about the same, 4% viewed e-cigarettes as more harmful than cigarettes, and 1% did not know. Compared with those with other perceptions of e-cigarette harm, dual users who perceived e-cigarettes as less harmful were more likely to switch to exclusive e-cigarette use and were less likely to switch to exclusive cigarette use one year later.

43. Majeed, et al. (2017) considered results in 2012 and 2015 for both non-smokers and an over-sampled group of smokers.[20] The percentage of adults who viewed e-cigarettes as less harmful than cigarettes was 39% in 2012 and 31% in 2015, and for smokers these percentages were 45% in 2012 and 36% in 2015. There was a large change in the percentage of adults who believed the risks to be about the same, from 12% in 2012 up to 36% in 2015. For smokers, that increase was from 11% in 2012 to 31% in 2015. There was a drop in the "don't know" percentages from 48% to 30% overall, and from 44% to 29% for smokers. The percentage of those who believed that e-cigarettes cause more harm than cigarettes remained low at 1% in 2012 and 4% in 2015 for both the full sample and for smokers.

44. Huang et al. (2019) found that in two nationally representative multiyear cross-sectional surveys of US adults, the percentage who viewed e-cigarettes as being as harmful as or more harmful than cigarettes increased from 2012 to 2017.[21] In the Tobacco Products and Risk Perceptions Survey (TPRPS) data, the proportion of adults who perceived e-

[20] Ban A. Majeed, et al. 2017. "Changing Perceptions of Harm of E-Cigarettes Among U.S. Adults, 2012-2015," *Am J. Prev. Med*., Vol 52, No. 3, pp. 331-338.
[21] Jidong Huang, et al. 2019. "Changing Perceptions of Harm of E-Cigarette vs. Cigarette Use Among Adults in 2 US National Surveys from 2012 to 2017, Tobacco Products and Risk Perceptions Survey and Health Information National Trends Survey," *JAMA Network Open*, Vol. 2, No. 3, pp. 1-12.

cigarettes to be as harmful as cigarettes increased from 11.5% in 2012 to 36.4% in 2017 and the percentage of those who perceived e-cigarettes to be more harmful than cigarettes increased from 1.3% in 2012 to 4.3% in 2017. For the Health Information National Trends Survey (HINTS) data, the proportion of adults who perceived e-cigarettes to be as harmful as cigarettes increased from 46.4% in 2012 to 55.6% in 2017; and those who perceived e-cigarettes to be more harmful than cigarettes increased from 2.8% in 2012 to 9.9% in 2017. One difference in the surveys is that there is a "don't know" option in TPRPS but not in HINTS.

45. Nyman (2019) reported harm beliefs in 2017 and 2018 based on the U.S. Tobacco Products and Risk Perceptions Survey (TPRPS).[22] Between 2017 and 2018, the percentage of adults perceiving e-cigarettes to be as harmful as cigarettes increased from 36.4% to 43.0%. The percentage of adults perceiving e-cigarettes to be more harmful than cigarettes also increased from 2.4% to 4.4% and the percentage perceiving e-cigarettes to be much more harmful than cigarettes increased from 1.9% to 3.7%.

46. Malt, et al. (2020) provide a review of the harm beliefs of US adults for e-cigarettes in three waves of the nationally representative Population Assessment of Tobacco and Health (PATH) study data.[23] In wave 1 from September 2013 to December 2014, 54% regarded e-cigarettes as being as harmful as or more harmful than cigarettes, and 41% viewed them as less harmful than cigarettes. In wave 2 from October 2014 to October 2015, 65% regarded e-cigarettes as being as harmful as or more harmful than cigarettes,

[22] Amy L. Nyman. 2019. "Perceived Comparative Harm of Cigarettes and Electronic Nicotine Delivery Systems," JAMA Network Open, Vol. 2, No. 11, pp. 1-4.
[23] Layla Malt, et al. 2020. "Perception of the Relative Harm of Electronic Cigarettes Compared to Cigarettes Amongst US Adults from 2013 to 2016: Analysis of the Population Assessment of Tobacco and Health (PATH) Study Data," *Harm Reduction Journal,* Vol. 17, No. 65, pp. 1-12.

and 32% considered them to be less harmful than cigarettes. The degree of beliefs that e-cigarettes are less harmful than cigarettes continued to decline to 25% in wave 3 from October 2015 to October 2016, with the percentage considering e-cigarettes as being as harmful as or more harmful than cigarettes increasing to 73% in October 2015. The "don't know" responses constituted the residual for each of these surveys. The authors conclude: "in this study, the proportion of US adults who incorrectly perceived e-cigarettes as equal to, or more, harmful than cigarettes increased steadily regardless of smoking or vaping status. Current adult smokers appear to be poorly informed about the relative risks of e-cigarettes yet have potentially the most to gain from transitioning to these products. The findings of this study emphasize the urgent need to accurately communicate the reduced relative risk of e-cigarettes compared to continued cigarette smoking and clearly differentiate absolute and relative harms. Further research is required to elucidate why the relative harm of e-cigarettes is misunderstood and continues to deteriorate."

47. Viscusi (2016, 2020) framed the question in terms of whether e-cigarettes pose lower risks than conventional cigarettes rather than lower levels of harm.[24] The results in both 2014 and 2019 were that 52% viewed e-cigarettes as being somewhat less risky or much less risky. The fraction who believed that e-cigarettes are more risky rose from 2% in 2014 to 11% in 2019, and the fraction who viewed e-cigarettes as just as risky was 44% in 2014 and 34% in 2019. In each case there was strong dependence of risk beliefs for e-cigarettes on respondents' risk assessment for conventional cigarettes. In particular,

[24] W. Kip Viscusi. 2016. "Risk Beliefs and Preferences for E-Cigarettes," *American Journal of Health Economics*, Vol. 2, No. 2, pp. 213-240. W. Kip Viscusi. 2020. "Electronic Cigarette Risk Beliefs and Usage after the Vaping Illness Outbreak," *Journal of Risk and Uncertainty*, Vol. 60, No. 3, pp. 259-279.

consumers' beliefs reflected a weight of about two-thirds on their cigarette risk beliefs when forming their e-cigarette risk beliefs.

Implications of the UK and US E-Cigarette Perception Studies

48. The percentage of the respondents who perceive e-cigarettes as being less harmful than cigarettes depends on the time period, the sample group, and the structure of the survey question. Including a "don't know" response decreases the percentage of respondents who commit to making a comparison. Surveys that are restricted to those who are familiar with e-cigarettes generate higher levels of comparative responses.

49. There are three principal implications of the survey results. First, a substantial segment of the population view e-cigarettes as posing equivalent risks to conventional cigarettes or even greater risks, which is inconsistent with the current scientific evidence and the prevailing public health opinions. Second, both in the UK and in the US, the proportion of the population who consider e-cigarettes to be as harmful or more harmful than conventional cigarettes has been increasing over time. Third, there is evidence that these continued misperceptions of the estimated risk of e-cigarettes are negatively correlated with e-cigarette use, with respondents who have these views being less likely to use e-cigarettes.

V. NEW EVIDENCE ON E-CIGARETTE PERCEPTIONS

50. A series of surveys were commissioned by British American Tobacco in 2020 to analyze the current level of harm beliefs in selected European markets. The principal objectives of the surveys were to ascertain the harm beliefs regarding e-cigarettes and the relationship of these beliefs to e-cigarette usage. In addition, the survey also asked

respondents' questions regarding their awareness, use and perceptions of heated tobacco products and oral nicotine pouches. I assisted in the design of the survey questions. The samples consisted of adult members of online survey panels. The countries included were the UK, Belgium, Denmark, the Netherlands, France, Germany, and Italy.

51. To be included in the sample, the respondent had to answer affirmatively to all of the following: (1) that they had smoked more than 100 cigarettes in their lifetime; (2) that they had heard of e-cigarettes; and (3) that they were either a current smoker, a current smoker and vaper, or a former smoker that currently vapes. As noted above, while not included as part of the screening of the sample (so as to avoid potentially limiting the sample size, given that these products are newer to the market and generally less used than e-cigarettes), the survey also asked questions regarding respondents' awareness, use and perceptions of heated tobacco products and oral nicotine pouches. After limiting the multi-country sample to those who passed these sample screens, the sample consisted of 1,073 respondents in Denmark, 1,477 respondents in Germany, and 1,500 respondents in each of the other five countries. The analysis below focuses on the pooled sample. Appendix A presents the demographic characteristics of the sample.

52. Table 1 provides overview statistics regarding product use and harm beliefs. Almost two-thirds of the sample use e-cigarettes currently, and 88% have either tried or currently use e-cigarettes. This high rate of product usage is a consequence of the sample screen. The harm perceptions reflect the beliefs of these groups. As also indicated in Figure 1, 57% of the sample view e-cigarettes as less harmful than cigarettes, and 43% consider them to be the same as or more harmful than cigarettes. For simplicity, all figures below will have numbers that correspond to the table of results that they are illustrating.

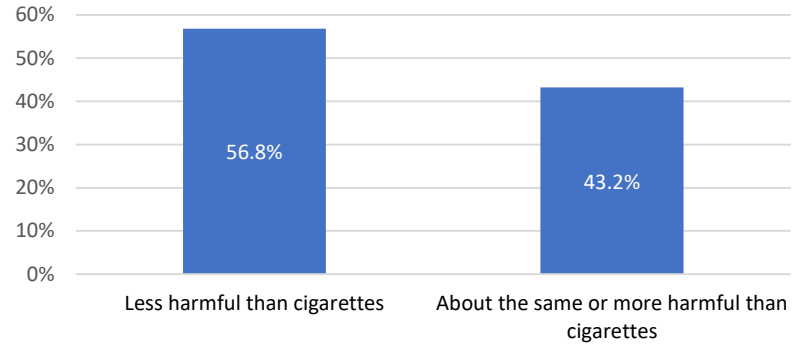
Table 1. **Product use and relative harm belief percentage**

	E-Cigarettes
Ever heard of the product *	100
Description of use **	
- Never tried the product	11.5
- Tried, but never use now	22.3
- Use the product currently	66.2
- Tried, regardless of current use	88.5
Harm relative to cigarettes ***	
- Less harmful than cigarettes	56.8
- About the same as cigarettes	35.5
- More harmful than cigarettes	7.7
- Same or more harmful	43.2

* Knowledge of e-cigarettes was required to participate in the survey.
** Those who have never heard of the product are assumed never to have tried it.
*** Harm beliefs are percentages of the subset of respondents who have heard of the product.

53. Table 1 indicates that a substantial portion of respondents perceive e-cigarettes to be the same as or more harmful than cigarettes. Since the sample consists of a disproportionate share of e-cigarette users, who would be expected to choose this behavior based on perceived lower levels of harm of the product, these results are likely to understate these perceptions for the general population.

Figure 1. **Estimated harm of e-cigarettes compared to cigarettes**

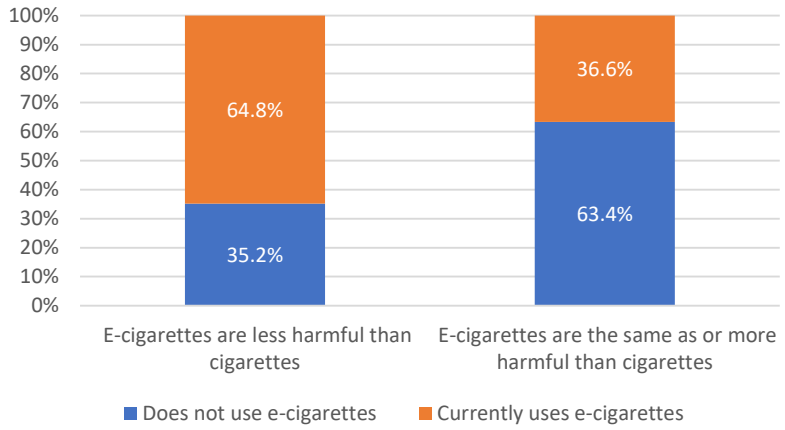


54. The relationship between product use and harm beliefs is examined in Table 2. The first two columns pertain to the beliefs of cigarette smokers. Half of the smokers in the sample use e-cigarettes and half of them do not. For cigarette smokers who consider e-cigarettes to be less harmful than cigarettes, 65% currently use e-cigarettes and 35% do not. In contrast, for current cigarette smokers who consider the harm levels from e-cigarettes to be the same or more harmful compared to cigarettes, 37% currently use e-cigarettes and 63% do not. Figure 2 also summarizes these harm belief results. The results for current non-smokers in the final two columns of Table 2 are less instructive, as all those who are non-smokers necessarily use e-cigarettes regardless of their harm beliefs or they will not be included in the sample.

Table 2. **Current or former cigarette smokers and their e-cigarette use percentage**

	Results for Current cigarette smokers		Results for Current non-smokers	
	Does not use product	Currently uses product	Does not use product	Currently uses product
E-Cigarette users	50.0	50.0	0	100
- Less harmful than cigarettes	35.2	64.8	0	100
- Same or more harmful	63.4	36.6	0	100

Figure 2. **Harm Beliefs of Current Cigarette Smokers**



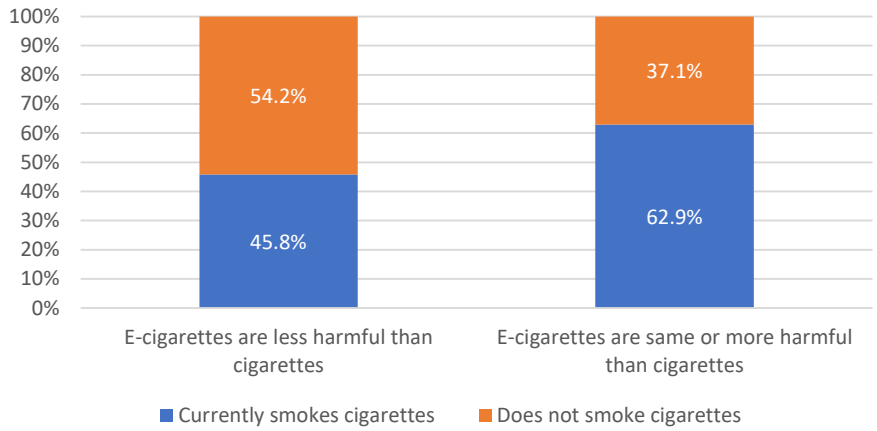
55. Table 3 and Figure 3 present the distribution of usage of cigarettes for e-cigarette users based on their level of harm beliefs. Overall, 51% of e-cigarette users in the sample currently smoke cigarettes, and 49% do not. For those who use e-cigarettes, having low levels of comparative harm beliefs is associated with not smoking cigarettes. The largest harm belief category among e-cigarette users is the less harmful group, for which 54% do not smoke cigarettes and 46% do. The pattern is strongly reversed for those who consider the risks to be just as harmful or more harmful, as 63% of this group currently smoke cigarettes and 37% do not smoke cigarettes.

Table 3. **Current or former cigarette smokers percentage, by use and harm perceptions of e-cigarettes**

	Observations	Currently smokes cigarettes	Does not smoke cigarettes
E-Cigarette users	6,650	51.1	48.9
- Less harmful than cigarettes	4,573	45.8	54.2
- About the same as cigarettes	1,634	73.3	26.7
- More harmful than cigarettes	443	24.4	75.6

E-Cigarette non-users	3,400	100	0
Distribution for all respondents	10,050	67.6	32.4

Figure 3. **Harm beliefs of current and former cigarette smokers**

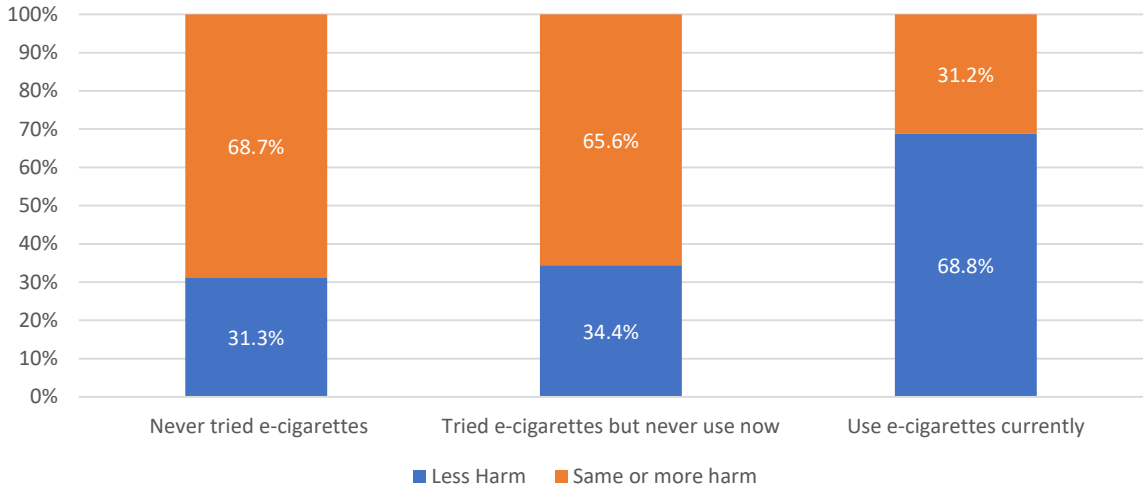


56. An alternative perspective on these relationships is the distribution of harm beliefs shown in Table 4 and Figure 4, conditional on different levels of e-cigarette usage. Those who currently use e-cigarettes are most likely to perceive that they are less harmful than cigarettes, with 69% of current e-cigarette users perceiving them to be less harmful than cigarettes and 31% of current e-cigarette users perceiving e-cigarettes to be just as harmful or more harmful than cigarettes. The least favorable assessments of the harmfulness of e-cigarettes are by those who have never tried the product, with only 31% of this group of those who have never used e-cigarettes considering e-cigarettes to be less harmful than cigarettes, and 69% considering e-cigarettes to be just as harmful or more harmful than cigarettes.

Table 4. **Harm beliefs relative to cigarettes percentage, by e-cigarette use**

	Observations	Less harm	Same harm	More harm	Same or More
E-Cigarettes	10,050				
- Never tried the product	1,155	31.3	55.8	12.8	68.7
- Tried, but never use now	2,245	34.4	57.5	8.1	65.6
- Use the product currently	6,650	68.8	24.6	6.7	31.2
- Tried, regardless of current use	8,895	60.1	32.9	7.0	39.9

Figure 4. **Estimated harm of e-cigarettes compared to cigarettes by use of product**



57. The linkage of harm beliefs to more measures of product usage is examined in Table 5 and Figures 5a, 5b, and 5c. Among those who smoke cigarettes but do not use e-cigarettes, 67% view e-cigarettes as the same as or more harmful than cigarettes. However, 76% of those who use e-cigarettes but not cigarettes consider e-cigarettes to be less harmful than cigarettes. By comparison, among those who both smoke cigarettes and use e-cigarettes, 62% consider e-cigarettes to be less harmful than cigarettes.

Cigarette smokers who do not use e-cigarettes are more likely to believe that e-cigarettes are at least as harmful as cigarettes, by a two-to-one margin.

Table 5. **Percentage distribution of harm beliefs for different groups of usage of cigarettes and e-cigarettes**

E-Cigarettes are:	Less harmful than cigarettes	Same or more harmful than cigarettes	Observations
Product use:			
- Smokes cigarettes, not e-cig	33.4	66.6	3,400
- E-Cigarettes, not cigarettes	76.3	23.7	3,252
- Both e-cigarettes and cigarettes	61.6	38.4	3,398

Figure 5A. **Estimated comparative harm beliefs of smokers of cigarettes and/or e-cigarette users**

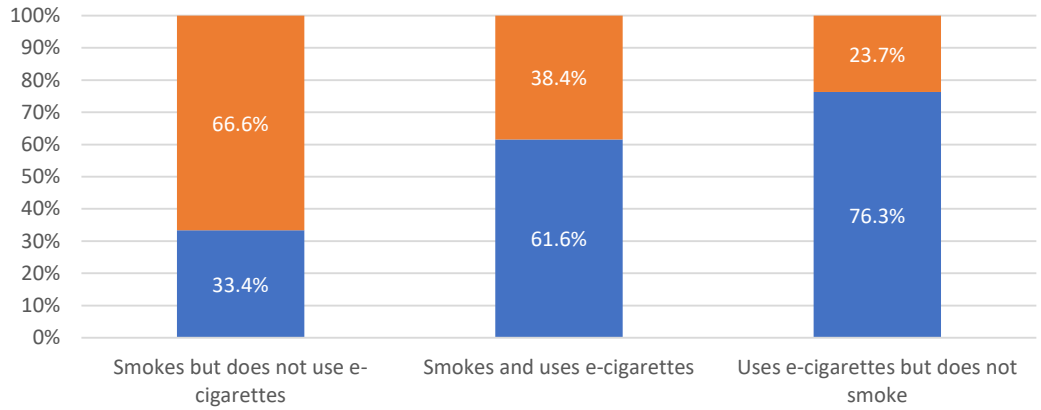


Figure 5B. **Harm beliefs of those who use e-cigarettes but do not smoke cigarettes**

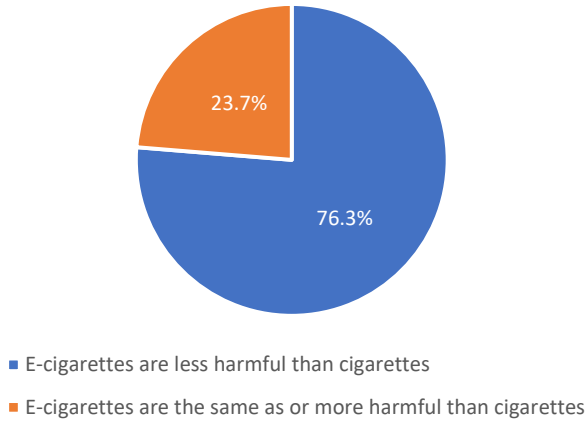
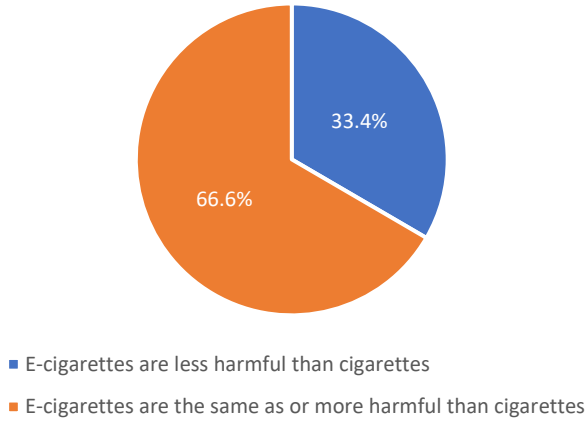


Figure 5C. **Harm beliefs of those who smoke cigarettes and do not use e-cigarettes**



58. The implication of Tables 1-5 and their figure counterparts is that beliefs that e-cigarettes are less harmful than cigarettes are correlated with e-cigarette usage, as well as with the combination of e-cigarette usage and not smoking cigarettes.

59. To better analyze the impact of risk perceptions on current e-cigarette use, Table 6 presents regression results in which the dependent variable is a 0-1 indicator for current product use, and the explanatory variables consist of harm beliefs, countries, and

demographic factors. These regressions in effect analyze factors that affect the probability that the respondent currently uses e-cigarettes. For some demographic variables, such as income and gender, a small number of respondents did not answer the question (Appendix A lists the missing data percentages for each variable). For these observations for which the respondent did not answer the question, I followed the standard statistical practice of including these responses in the statistical analysis but creating a 0-1 indicator variable to address the fact that an observation on this particular variable is missing for the particular respondent.

60. Controlling for the variables included in the regression in Table 6, those who consider e-cigarettes to be less harmful than cigarettes are 33% more likely to currently use e-cigarettes. This relationship is statistically significant with a 95% confidence level, a test that is noted by at least two asterisks in the regression results in this report (three asterisks reflect a 99% level). There are no statistically significant country effects. For this and in subsequent regressions, the UK is the excluded country, which means that any country effects are measured relative to the UK. Usage of e-cigarettes rises with age, but then declines for those age 60+.

Table 6. **Regressions predicting the probability that respondent CURRENTLY USES e-cigarettes, based on harm beliefs, country, and demographics**

	E-Cigarette yes use
E-cigarette less harmful	0.3260***
	(0.0090)
Belgium	0.0066
	(0.0170)
Denmark	0.0090
	(0.0177)
Netherlands	-0.0210

	(0.0163)
France	0.0213
	(0.0161)
Germany	0.0174
	(0.0161)
Italy	0.0014
	(0.0162)
Age	0.0011**
	(0.0005)
Age 60+	-0.0360**
	(0.0159)
Income	0.0010***
	(0.0002)
Income €150,000+	0.1087***
	(0.0242)
Years education	0.0127***
	(0.0020)
Black	-0.1276***
	(0.0300)
Asian	-0.0440
	(0.0294)
Other	-0.0098
	(0.0268)
Female	-0.0255***
	(0.0091)
Married	0.0114
	(0.0128)
Widowed	-0.0175
	(0.0296)
Divorced	-0.0301
	(0.0186)
Separated	-0.0042
	(0.0279)
Partner	0.0217
	(0.0147)
Missing income	0.0187
	(0.0177)
Missing education	0.2332***
	(0.0511)
Missing race	0.0714*
	(0.0399)
Missing female	-0.1824*
	(0.1065)
Missing relationship	-0.0283
	(0.0438)
Constant	0.1959***

	(0.0373)
Observations	10,050
R-squared	0.15

Standard errors in parentheses; * significant at 10%; ** significant at 5%; *** significant at 1%
Country effects are relative to the United Kingdom, the excluded country variable.

61. Given the pivotal role of whether the respondent believes that e-cigarettes are less harmful than cigarettes, the regressions in Table 7 analyze the relationship of the 0-1 variable for whether the respondent perceives e-cigarettes as less harmful than cigarettes. Also included are the variables for the different countries and demographic groups. Relative to the UK sample, respondents in Belgium, Denmark, the Netherlands, France, and Germany are significantly less likely to believe that e-cigarettes are less harmful than cigarettes. Given the efforts by Public Health England and other public health organizations in the UK to communicate the relative risk profile of e-cigarettes as compared to cigarettes, this pattern is consistent with a possible impact of these efforts on harm beliefs. The greatest disparity is for respondents in Belgium, as they are 25% less likely to regard e-cigarettes as less harmful. Respondents also are more likely to regard e-cigarettes as less harmful if they are age 60+ or have high income but are not in the top income group.

Table 7. **Regressions predicting the probability that the respondent believes e-cigarettes are LESS HARMFUL than cigarettes, based on country and demographics**

	E-Cigarettes less harmful
Belgium	-0.2596***
	(0.0188)
Denmark	-0.1356***
	(0.0197)
Netherlands	-0.0862***
	(0.0182)
France	-0.0513***
	(0.0179)
Germany	-0.1216***

	(0.0179)
Italy	-0.0029
	(0.0181)
Age	-0.0009*
	(0.0005)
Age 60+	0.0813***
	(0.0177)
Income	0.0008***
	(0.0002)
Income €150,000+	-0.0903***
	(0.0269)
Years education	-0.0031
	(0.0022)
Black	-0.0528
	(0.0335)
Asian	-0.1280***
	(0.0327)
Other	-0.0394
	(0.0299)
Female	-0.0723***
	(0.0101)
Married	-0.0034
	(0.0143)
Widowed	-0.0228
	(0.0330)
Divorced	0.0154
	(0.0208)
Separated	0.0072
	(0.0311)
Partner	0.0393**
	(0.0164)
Missing income	0.0126
	(0.0197)
Missing education	-0.0386
	(0.0570)
Missing race	-0.0138
	(0.0445)
Missing female	-0.3318***
	(0.1187)
Missing relationship	0.0619
	(0.0489)
Constant	0.7316***
	(0.0409)
Observations	10,050
R-squared	0.04

Standard errors in parentheses; * significant at 10%; ** significant at 5%; *** significant at 1%
Country effects are relative to the United Kingdom, the excluded country variable.

62. Whether e-cigarette use is related to smoking status is examined in the regressions in Table 8, where the dependent variable is the 0-1 indicator variable for whether the respondent is a current smoker. If the respondent currently uses e-cigarettes, he or she is 48% less likely to also be a current smoker. These results are consistent with e-cigarettes serving as an alternative for conventional cigarettes given the sample screens that required all people to be a current or former smoker. Given the cross-sectional nature of the data, the timing of the transition to use of e-cigarettes cannot be determined.

Table 8. **Regressions predicting the probability that the respondent is a CURRENT CIGARETTE SMOKER, based on e-cigarette USE, country, and demographics**

	Smoker
E-cigarette yes use	-0.4814***
	(0.0085)
Belgium	0.0337**
	(0.0153)
Denmark	0.0730***
	(0.0161)
Netherlands	0.0064
	(0.0148)
France	0.0024
	(0.0146)
Germany	0.0014
	(0.0146)
Italy	-0.0217
	(0.0147)
Age	-0.0054***
	(0.0004)
Age 60+	-0.0612***
	(0.0144)
Income	0.0000
	(0.0002)
Income €150,000+	-0.2013***
	(0.0219)
Years education	0.0095***
	(0.0018)
Black	-0.0229

	(0.0273)
Asian	0.0611**
	(0.0267)
Other	0.0207
	(0.0244)
Female	-0.0101
	(0.0083)
Married	0.0212*
	(0.0116)
Widowed	0.0295
	(0.0269)
Divorced	0.0021
	(0.0169)
Separated	-0.0180
	(0.0254)
Partner	-0.0544***
	(0.0133)
Missing income	-0.0569***
	(0.0160)
Missing education	0.1229***
	(0.0465)
Missing race	-0.0077
	(0.0363)
Missing female	0.0037
	(0.0968)
Missing relationship	-0.0539
	(0.0398)
Constant	1.1053***
	(0.0336)
Observations	10,050
R-squared	0.29

Standard errors in parentheses; * significant at 10%; ** significant at 5%; *** significant at 1%
Country effects are relative to the United Kingdom, the excluded country variable.

63. Table 9 reports a regression on a closely related matter regarding exclusive e-cigarette usage. The dependent variable is a 0-1 variable for whether the respondent currently uses e-cigarettes and also does not smoke cigarettes. The principal variable of interest is whether the respondent considers e-cigarettes to be less harmful than cigarettes. Those who have this belief are 9% more likely to be an e-cigarette user and not smoke conventional cigarettes. The country effects relative to the UK are also interesting. All

effects that are statistically significant are negative. The four statistically significant relationships are for Belgium, the Netherlands, Germany, and Italy, all of which have a lower likelihood of respondents using e-cigarettes and not also smoking compared to the UK. Together with the earlier results on risk beliefs, these findings indicate that in the UK people are more likely to perceive e-cigarettes as less harmful than cigarettes and are also more likely to use e-cigarettes and not also smoke even after controlling for this difference in beliefs, compared to these other countries.

Table 9. **Regressions predicting the probability that the respondent CURRENTLY USES e-cigarettes for the subsample that DOES NOT SMOKE CIGARETTES, for exclusive use of product**

	E-Cigarette yes only
E-cig less harmful	0.0935***
	(0.0167)
Belgium	-0.1904***
	(0.0264)
Denmark	0.0200
	(0.0259)
Netherlands	-0.0758***
	(0.0232)
France	-0.0268
	(0.0215)
Germany	-0.1053***
	(0.0221)
Italy	-0.2933***
	(0.0220)
Age	-0.0017**
	(0.0007)
Age 60+	-0.0018
	(0.0206)
Income	-0.0029***
	(0.0002)
Income €150,000+	-0.2022***
	(0.0334)
Years education	-0.0078***
	(0.0029)
Black	0.0990**
	(0.0485)

Asian	-0.0035
	(0.0554)
Other	-0.0314
	(0.0431)
Female	-0.0090
	(0.0130)
Married	-0.0076
	(0.0191)
Widowed	-0.0163
	(0.0421)
Divorced	-0.0304
	(0.0261)
Separated	-0.0469
	(0.0393)
Partner	-0.0239
	(0.0208)
Missing income	-0.0631***
	(0.0238)
Missing education	-0.0754
	(0.0698)
Missing race	-0.0323
	(0.0527)
Missing female	-0.5457
	(0.3379)
Missing relationship	-0.0459
	(0.0594)
Constant	1.1903***
	(0.0560)
Observations	3,252
R-squared	0.37

Standard errors in parentheses; * significant at 10%; ** significant at 5%; *** significant at 1%
Country effects are relative to the United Kingdom, the excluded country variable.

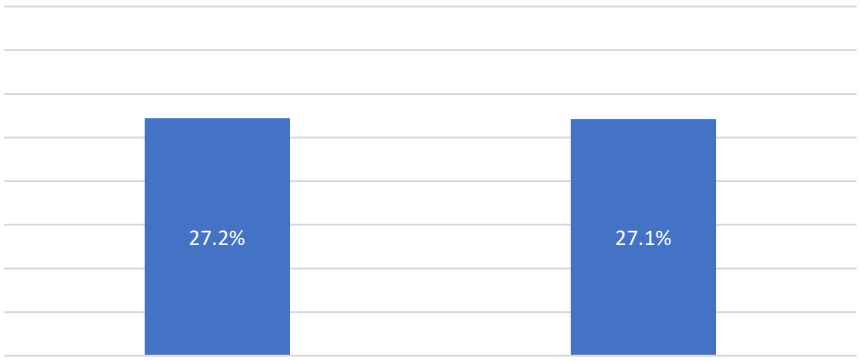
64. The surveys also elicited respondents' reasons for never trying e-cigarettes. For the sample of respondents in Table 10 who have never tried the product, the main reasons given are that they do not know enough about e-cigarettes or do not think that e-cigarettes are any less harmful than cigarettes, each of which were mentioned by 27% of the respondents. Just under 17% of the sample indicate that they do not want to quit smoking, and 16% believe that e-cigarettes will not help them quit. Cost is a minor

concern voiced by 10% of respondents. Figure 10 summarizes the most prominent main reasons for never trying e-cigarettes.

Table 10. **Percentage distribution of the main reason for decision to have NEVER TRIED e-cigarettes**

What is the main reason for you not trying	E-Cigarette
I do not know enough about them	27.2
I do not want to quit smoking	16.9
I do not think that they are any less harmful than cigarettes	27.1
They cost too much	9.7
I do not think that they would help me to quit or cut down smoking	15.8
Other	3.3
Number of observations	1,155

Figure 10. **Main reason given by respondents for never having tried e-cigarettes**



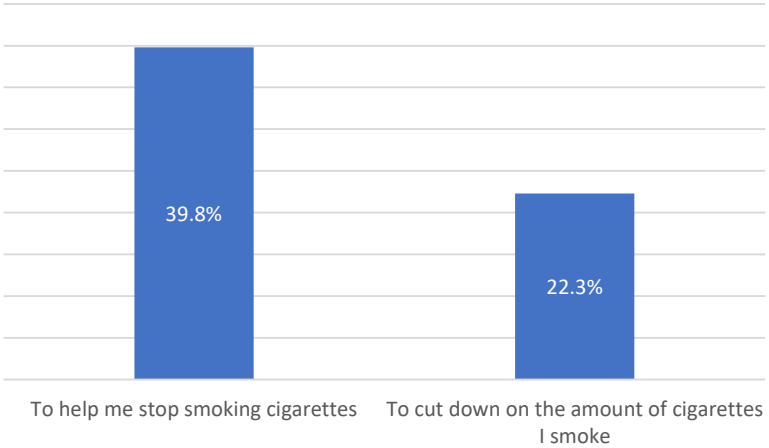
65. The stated reasons for currently using e-cigarettes shown in Table 11 are consistent with e-cigarettes serving as an alternative for conventional cigarettes. A combined total of 62% of the current users indicate that they are using e-cigarettes to either help them stop

smoking cigarettes (40%) or to cut down on the number of cigarettes smoked (22%). Figure 11 illustrates these key results. Saving money and the availability of a variety of flavors rank next in importance. Lower on the list are responses more closely related to exposure to others and acceptability of using e-cigarettes, as 8% indicate that e-cigarettes can be used in more places and 6% reference the absence of environmental tobacco smoke.

Table 11. **Percentage distribution of the main reason for decision to CURRENTLY USE e-cigarettes**

What is the main reason for you using	E-Cigarette
To help me stop smoking cigarettes	39.8
To cut down on the amount of cigarettes that I smoke	22.3
[To help me stop or to cut down]	62.0
To save money	11.6
Because they are available in better flavors than cigarettes	10.2
Convenience, e-cigarettes can be used in more places	8.1
To not expose people nearby me to cigarette smoke	5.5
Other	2.6
Number of observations	6,650

Figure 11. **Main reason for decisions to currently use e-cigarettes**



VI. NEW EVIDENCE ON HARM PERCEPTIONS FOR HEATED TOBACCO PRODUCTS AND ORAL NICOTINE POUCHES

66. The respondents to the surveys also answered questions regarding heated tobacco products and oral nicotine pouches. Both because of the sample screens and the lower overall usage of these products, the results often pertain to a subset of the overall sample.

Table 12. **Product use and relative harm belief percentage, for each of two products**

	Heated tobacco products	Oral nicotine pouches
Ever heard of the product*	64.8	47.2
Description of use **		
- Never tried the product	61.9	75.3
- Tried, but never use now	21.2	15.7
- Use the product currently	16.9	9.0
- Tried, regardless of current use	38.1	24.7

Harm relative to cigarettes ***		
- Less harmful than cigarettes	43.6	48.7
- About the same as cigarettes	48.7	40.3
- More harmful than cigarettes	7.7	11.0
- Same or more harmful	56.4	51.3

* Knowledge of e-cigarettes was required to participate in the survey.
** Those who have never heard of the product are assumed never to have tried it.
*** Harm beliefs are percentages of the subset of respondents who have heard of the product.

67. As indicated in Table 12, 66% of respondents had heard of heated tobacco products, and only 47% had heard of oral nicotine pouches. The data in Table 12 and Figures 12A and 12B regarding the respondent's use of the product and harm perceptions only pertain to the subsample of respondents who indicated that they had heard of each of the products. Among these groups, 38% had tried heated tobacco products, and 25% had tried oral nicotine pouches. Beliefs are roughly evenly divided between perceptions that the product is less harmful than cigarettes and perceptions that the product is just as harmful or more harmful. For heated tobacco products, 44% view them as less harmful than cigarettes, and 56% consider them to be the same or more harmful than cigarettes. For oral nicotine products, 49% consider them to be less harmful than cigarettes, and 51% consider them to be the same or more harmful than cigarettes.

Figure 12A. **Estimated harm of heated tobacco products compared to cigarettes**

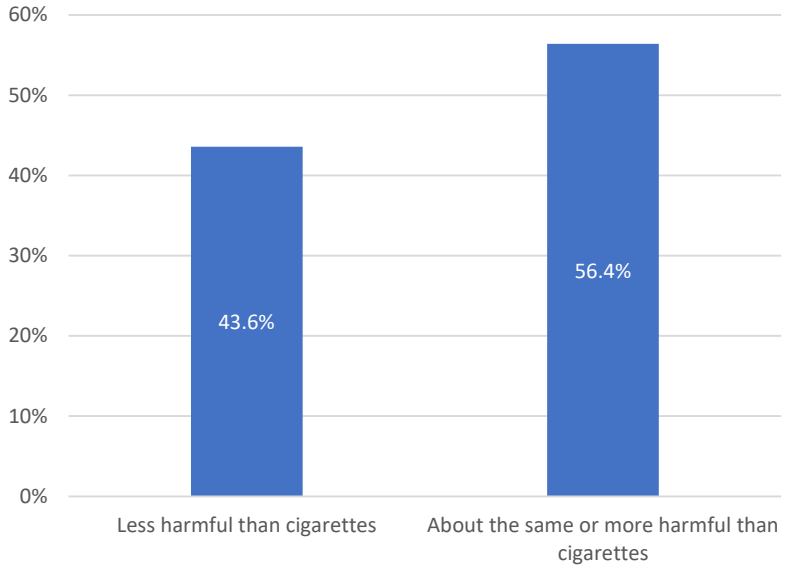
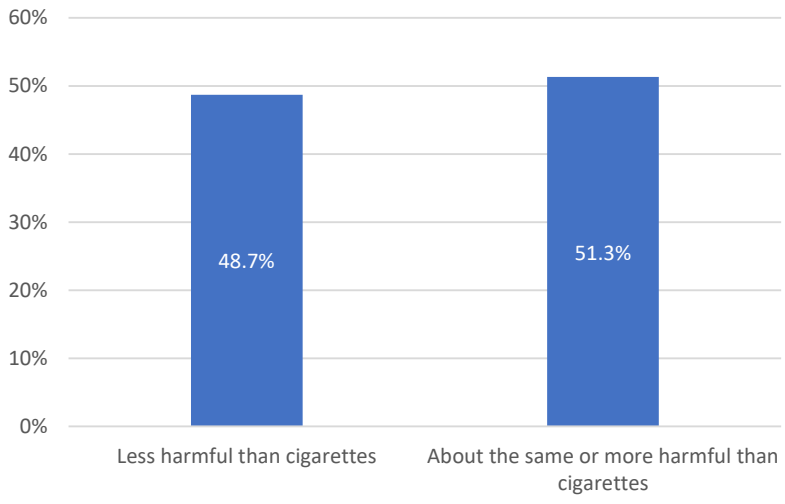


Figure 12B. **Estimated harm of oral nicotine pouches compared to cigarettes**



68. The distribution of harm perceptions varies depending on product usage, as indicated in Table 13 and Figures 13A and 13B. The product usage statistics are at the top of each

panel of Table 13. Overall, 14% of current cigarette smokers currently use heated tobacco products, and 22% of former smokers currently use heated tobacco products. Among those who believe that heated tobacco products are less harmful than cigarettes, 67% of current smokers currently use heated tobacco products, and 33% do not, while for former smokers who believe that heated tobacco products are less harmful than cigarettes, 51% currently use heated tobacco products and 49% do not. Usage among those who believe that heated tobacco products are the same as or more harmful than cigarettes is much lower—only 15% among smokers and 16% among former smokers in this belief group use heated tobacco products. Only 7% of current smokers currently use oral nicotine pouches and 14% of former smokers currently use oral nicotine pouches. For those who believe that oral nicotine pouches are less harmful than cigarettes, the rate of usage is 19% for current smokers and 42% for former smokers. For those who believe that oral nicotine pouches are the same as or more harmful than cigarettes, the rate of product usage is 10% among current smokers and 16% among former smokers.

Table 13. **Current or former cigarette smokers and their alternative product use percentage, by product and harm belief for that product**

	Results for Current cigarette smokers		Results for former smokers	
	Does not use product	Currently uses product	Does not use product	Currently uses product
Heated tobacco users	85.6	14.4	78.0	22.0
- Less harmful than cigarettes	67.4	32.6	48.7	51.3
- Same or more harmful	84.8	15.2	84.0	16.0
Oral nicotine users	93.2	6.8	86.4	13.6
- Less harmful than cigarettes	80.8	19.2	58.0	42.0
- Same or more harmful	90.1	9.9	84.5	15.5

Figure 13A. **Harm Beliefs of Current Cigarette Smokers**

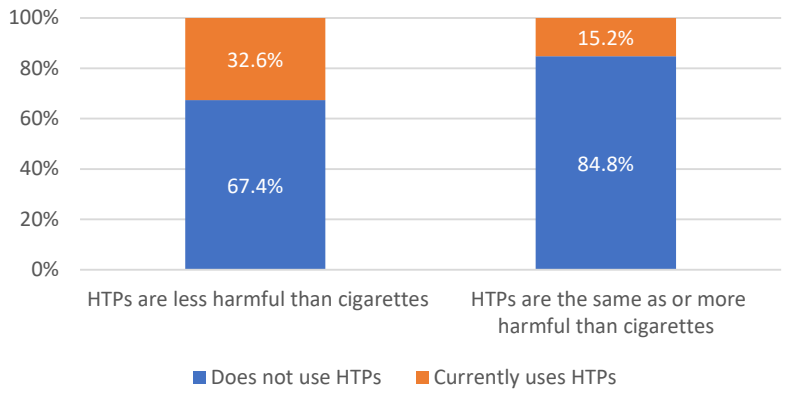
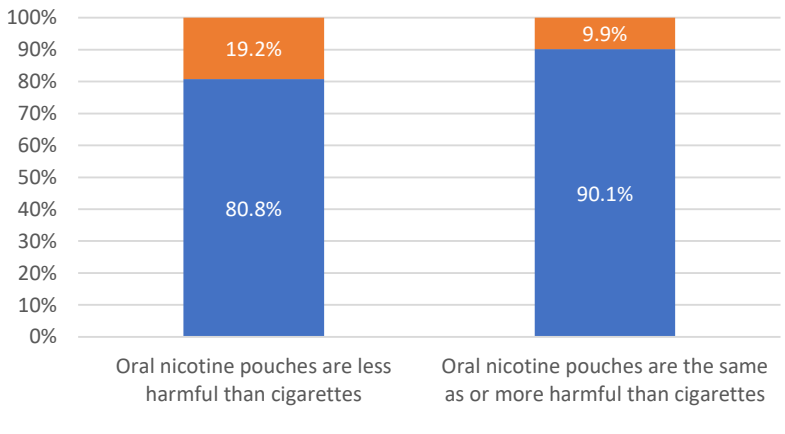


Figure 13B. **Harm Beliefs of Current Cigarette Smokers**



69. To explore the linkage between usage of these products and whether the respondent currently smokes cigarettes, Table 14 reports these statistics both overall as well as conditional on harm beliefs. The table and the Figures 14A and 14B illustrate the key results. Users of heated tobacco products and oral nicotine pouches are more likely to be former smokers. Among heated tobacco product users 42% do not currently smoke

cigarettes, as compared to 30% of non-users of heated tobacco products who do not currently smoke cigarettes; and 49% of oral nicotine pouch users do not currently smoke cigarettes, as compared to 31% of non-users of oral nicotine pouches who do not smoke cigarettes. Similarly, users of both heated tobacco and oral nicotine products have a 57% non-smoking rate.

70. For those who use heated tobacco products and oral nicotine pouches, perceiving these products as being less harmful than cigarettes is also associated with not smoking cigarettes. Among heated tobacco product users who believe that heated tobacco is less harmful than cigarettes, 49% do not currently smoke cigarettes; and 55% of oral nicotine pouch users who believe that the product is less harmful than cigarettes do not currently smoke cigarettes. This effect is diminished for those who believe that these products are the same or more harmful than cigarettes, such that 28% do not currently smoke cigarettes if they believe this about heated tobacco products and 36% do not currently smoke cigarettes if they believe this about nicotine pouches, as shown in Figure 14B.

Table 14. **Current or former cigarette smokers percentage, by use and harm perceptions of products, including multiple product users**

	Observations	Currently smokes cigarettes	Does not smoke cigarettes
Heated tobacco users	1,696	57.9	42.1
- Less harmful than cigarettes	1,130	50.6	49.4
- About the same as cigarettes	438	80.6	19.4
- More harmful than cigarettes	127	44.1	55.9
Heated tobacco non-users	8,354	69.6	30.4
Oral nicotine users	906	51.2	48.8
- Less harmful than cigarettes	629	45.5	54.5
- About the same as cigarettes	172	84.3	15.7
- More harmful than cigarettes	104	30.8	69.2
Oral nicotine non-users	9,144	69.3	30.7
Users of multiple products - Heated & Pouches	709	43.4	56.6
Distribution for all respondents	10,050	67.6	32.4

Figure 14A. **Harm beliefs of current and former cigarette smokers**

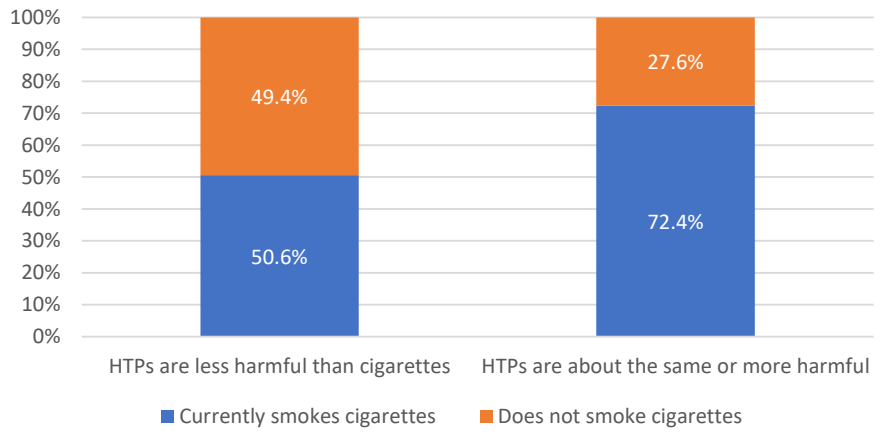
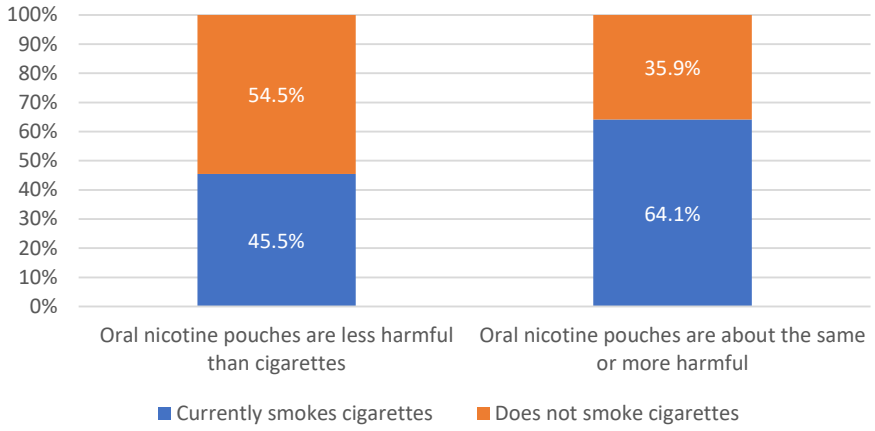


Figure 14B. **Harm beliefs of current and former cigarette smokers**



71. Table 15 and Figures 15A and 15B show the distribution of harm beliefs conditional on different levels of heated tobacco and oral nicotine products usage. In the case of heated tobacco products, 67% of those who use the product perceive that they are less harmful than cigarettes and 33% perceive that they are the same as or more harmful than cigarettes. In the case of oral nicotine pouches, 69.5% of those who use the product perceive that they are less harmful than cigarettes and 30.5% perceive that they are the same as or more harmful than cigarettes.

Table 15. **Harm beliefs relative to cigarettes percentage, by product use for each product**

	Observations	Less harm	Same harm	More harm	Same or More
Heated tobacco products	6,511				
- Never tried the product	2,685	34.7	57.7	7.6	65.3
- Tried, but never use now	2,131	36.6	55.7	7.9	63.4
- Use the product currently	1,695	66.7	25.8	7.5	33.3
- Tried, regardless of current use	3,826	49.9	43.4	7.7	50.1
Oral nicotine pouches	4,739				

- Never tried the product	2,256	46.9	43.4	9.8	53.1
- Tried, but never use now	1,578	39.4	48.3	12.3	60.6
- Use the product currently	905	69.5	19.0	14.5	30.5
- Tried, regardless of current use	2,483	50.4	37.6	12.0	49.6

Figure 15A. **Estimated harm of heated tobacco products compared to cigarettes by use of product**

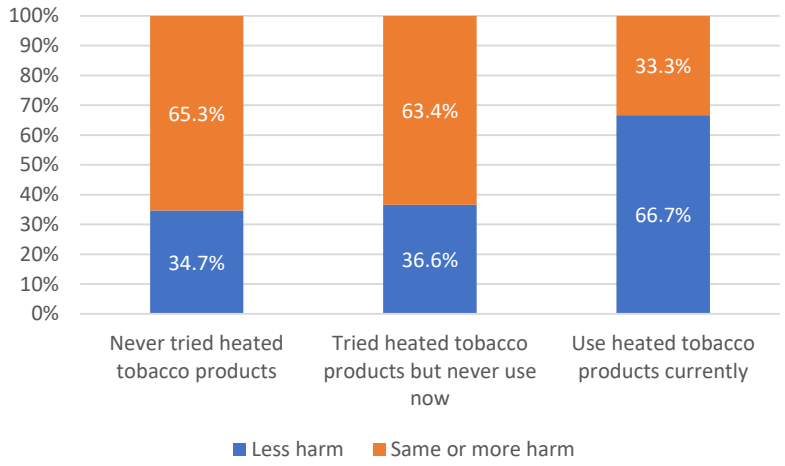
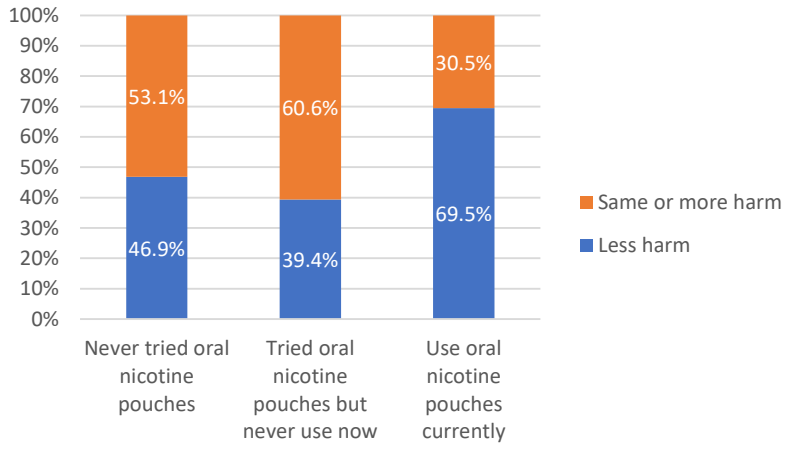


Figure 15B. **Estimated harm of oral nicotine pouches compared to cigarettes by use of product**



72. The final set of overall harm belief statistics in Table 16 analyzes the product use groups in conjunction with the harm beliefs. In the case of heated tobacco products, the percentage who believe that they are as harmful as or more harmful than cigarettes is 66% for those who smoke cigarettes and do not use heated tobacco products, 22% for those who use heated tobacco products and do not smoke cigarettes, 42% if they use both heated tobacco products and cigarettes, and 61% if they use neither heated tobacco products nor cigarettes. The remainder in each group believe that heated tobacco products are less harmful than cigarettes. In the case of oral nicotine products, the percentage who believe that they are as harmful as or more harmful than cigarettes is 57% for those who smoke cigarettes but do not use oral nicotine pouches, 22% for those who use oral nicotine pouches but do not smoke cigarettes, 38% for those who use both oral nicotine pouches and smoke cigarettes, and 53% for those who use neither oral nicotine pouches nor cigarettes.

Table 16. **Percentage distribution of harm beliefs for different groups of usage of cigarettes and other products**

Heated products are:	Less harmful than cigarettes	Same or more harmful than cigarettes	Observations
Product use:			
- Smokes cigarettes, not heated	34.1	65.9	3,467
- Heated, not cigarettes	78.2	21.8	714
- Both heated and cigarettes	58.3	41.7	981
- Neither heated nor cigarettes	39.2	60.8	1,349
Oral nicotine pouches are:	Less harmful than cigarettes	Same or more harmful than cigarettes	Observations
Product use:			
- Smokes cigarettes, not pouches	42.8	57.2	2,821
- Pouches, not cigarettes	77.6	22.4	442

- Both pouches and cigarettes	61.8	38.2	463
- Neither pouches nor cigarettes	46.7	53.3	1,013

73. Given the nature of the sampling screens, usage of heated tobacco products and oral nicotine pouch products is less common than is e-cigarette usage in this sample. Nevertheless, the patterns regarding the usage of these products and the relationship of product usage to perceptions of their degree of harm are instructive. Each of the products faces substantial barriers with respect to accurate understanding of the estimated risks that these alternative products pose as compared to the risks posed by conventional cigarettes that burn tobacco. Just over half of all respondents believe that these products pose risks of harm that are the same as or greater than those posed by cigarettes. The perceptions of harm are correlated with product usage in the expected manner, as respondents who believe that the products are less harmful than cigarettes are more likely to use them than are respondents who believe that they are just as harmful as cigarettes or more harmful. People who do not believe that these products pose less harm are less likely to try these products or to currently use them. This relationship also holds for cigarette smokers, as the failure to understand the comparative risk reduction that scientists estimate is provided by these products may deter their usage as an alternative to smoking cigarettes.

74. Table 17 presents regression results in which the dependent variable is a 0-1 indicator for current product use, and the explanatory variables consist of harm beliefs, country, and demographic factors. Those who perceive that heated tobacco products are less harmful than cigarettes are 15% more likely to be using heated tobacco products, while those who perceive nicotine pouches as being less harmful than cigarettes are 4% more likely to be

using them. There are several differences across countries in the usage of these products. All statistically significant effects reflect higher levels of usage than in the UK. Higher income and better educated respondents are also more likely to use each of these products.

Table 17. **Regressions predicting the probability that respondent CURRENTLY USES each of the products, based on harm beliefs, country, and demographics**

	Heated yes use	Pouch yes use
Heated less harmful	0.1473***	
	(0.0102)	
Pouch less harmful		0.0390***
		(0.0098)
Belgium	0.1755***	0.2034***
	(0.0211)	(0.0179)
Denmark	0.0132	0.0251
	(0.0216)	(0.0186)
Netherlands	0.0242	0.0464***
	(0.0181)	(0.0172)
France	0.0264	0.0339**
	(0.0184)	(0.0167)
Germany	0.1023***	0.0322*
	(0.0170)	(0.0168)
Italy	0.1550***	-0.0138
	(0.0167)	(0.0174)
Age	-0.0002	0.0006
	(0.0005)	(0.0005)
Age 60+	-0.0328*	-0.0295
	(0.0191)	(0.0198)
Income	0.0017***	0.0015***
	(0.0002)	(0.0002)
Income €150,000+	0.1976***	0.3044***
	(0.0247)	(0.0218)
Years education	0.0160***	0.0122***
	(0.0022)	(0.0021)
Black	-0.0932***	-0.0866***
	(0.0309)	(0.0260)
Asian	-0.0162	0.0566**
	(0.0304)	(0.0267)
Other	0.0063	0.0202
	(0.0291)	(0.0243)
Female	0.0080	0.0134

	(0.0101)	(0.0099)
Married	0.0370***	0.0076
	(0.0141)	(0.0142)
Widowed	-0.0268	-0.0126
	(0.0334)	(0.0317)
Divorced	0.0144	-0.0350
	(0.0221)	(0.0223)
Separated	0.0032	0.0825***
	(0.0317)	(0.0310)
Partner	-0.0039	-0.0160
	(0.0168)	(0.0165)
Missing income	0.0412*	0.0191
	(0.0232)	(0.0241)
Missing education	0.2838***	0.1371**
	(0.0670)	(0.0639)
Missing race	-0.0028	-0.0074
	(0.0475)	(0.0434)
Missing female	0.0782	-0.0535
	(0.1170)	(0.0825)
Missing relationship	-0.0405	-0.0301
	(0.0585)	(0.0525)
Constant	-0.2442***	-0.2289***
	(0.0412)	(0.0384)
Observations	6,511	4,739
R-squared	0.23	0.36

Standard errors in parentheses; * significant at 10%; ** significant at 5%; *** significant at 1%
Country effects are relative to the United Kingdom, the excluded country variable.

75. The regression results in Table 18 analyze the determinants of whether the respondent believes that the product is less harmful than cigarettes. The results of greatest interest are the differences across countries, all of which are relative to the UK. With a few exceptions, all country effects are negative and statistically significant, meaning that relative to the UK, the residents of these countries are less likely to perceive these two products as being less harmful than cigarettes.

Table 18. **Regressions predicting the probability that the respondent believes the product is LESS HARMFUL than cigarettes, based on country and demographics**

	Heated less harmful	Pouch less harmful
Belgium	-0.0313	-0.0076
	(0.0256)	(0.0267)
Denmark	-0.0470*	-0.1190***
	(0.0262)	(0.0277)
Netherlands	-0.1482***	-0.2388***
	(0.0219)	(0.0253)
France	-0.0928***	-0.1621***
	(0.0223)	(0.0248)
Germany	-0.0350*	-0.1541***
	(0.0206)	(0.0249)
Italy	0.1513***	-0.1238***
	(0.0202)	(0.0258)
Age	0.0023***	0.0020***
	(0.0006)	(0.0007)
Age 60+	-0.0409*	-0.0763***
	(0.0231)	(0.0295)
Income	0.0008***	0.0000
	(0.0002)	(0.0002)
Income €150,000+	0.3189***	0.3249***
	(0.0298)	(0.0322)
Years education	-0.0042	-0.0041
	(0.0027)	(0.0032)
Black	-0.1196***	-0.1056***
	(0.0375)	(0.0387)
Asian	-0.0148	-0.0563
	(0.0369)	(0.0397)
Other	-0.0031	-0.0928**
	(0.0353)	(0.0362)
Female	-0.0736***	-0.0570***
	(0.0123)	(0.0147)
Married	0.0266	0.0128
	(0.0171)	(0.0212)
Widowed	0.0432	0.0666
	(0.0405)	(0.0473)
Divorced	-0.0156	0.0142
	(0.0268)	(0.0332)
Separated	-0.0077	-0.0880*
	(0.0385)	(0.0461)
Partner	-0.0478**	-0.0252
	(0.0204)	(0.0246)
Missing income	-0.0293	-0.0300

	(0.0281)	(0.0359)
Missing education	0.0243	-0.1074
	(0.0813)	(0.0951)
Missing race	-0.0833	0.0607
	(0.0576)	(0.0646)
Missing female	-0.2186	-0.0328
	(0.1419)	(0.1230)
Missing relationship	-0.0226	-0.0066
	(0.0710)	(0.0783)
Constant	0.3762***	0.5648***
	(0.0498)	(0.0567)
Observations	6,511	4,739
R-squared	0.12	0.12

Standard errors in parentheses; * significant at 10%; ** significant at 5%; *** significant at 1%
Country effects are relative to the United Kingdom, the excluded country variable.

76. Whether the respondent is a current smoker is the dependent variable in the regression results in Table 19. These results for the full sample find that users of both heated tobacco products and oral nicotine pouches are less likely to be a current smoker, whether these products are included in the regression results individually or jointly. When both products are included in the final regression, heated tobacco users are 4% less likely to be a current smoker and users of oral pouches are 9% less likely to be a current smoker.

Table 19. **Regressions predicting the probability that the respondent is a CURRENT CIGARETTE SMOKER, based on alternative product USE, country, and demographics**

	Smoker	Smoker	Smoker
Heat yes use	-0.0685***		-0.0438***
	(0.0137)		(0.0148)
Pouch yes use		-0.1162***	-0.0926***
		(0.0195)	(0.0211)
Belgium	0.0758***	0.0827***	0.0833***
	(0.0176)	(0.0176)	(0.0176)
Denmark	0.0893***	0.0908***	0.0902***
	(0.0184)	(0.0184)	(0.0184)
Netherlands	0.0296*	0.0304*	0.0300*

	(0.0170)	(0.0170)	(0.0170)
France	0.0004	0.0012	0.0012
	(0.0167)	(0.0167)	(0.0167)
Germany	0.0180	0.0120	0.0158
	(0.0168)	(0.0167)	(0.0168)
Italy	-0.0094	-0.0236	-0.0152
	(0.0171)	(0.0169)	(0.0171)
Age	-0.0058***	-0.0058***	-0.0058***
	(0.0005)	(0.0005)	(0.0005)
Age 60+	-0.0593***	-0.0586***	-0.0599***
	(0.0165)	(0.0165)	(0.0165)
Income	-0.0005***	-0.0005***	-0.0004**
	(0.0002)	(0.0002)	(0.0002)
Income €150,000+	-0.2171***	-0.1912***	-0.1867***
	(0.0256)	(0.0264)	(0.0264)
Years education	0.0048**	0.0048**	0.0052**
	(0.0021)	(0.0021)	(0.0021)
Black	0.0420	0.0405	0.0387
	(0.0313)	(0.0313)	(0.0313)
Asian	0.1020***	0.1073***	0.1061***
	(0.0306)	(0.0306)	(0.0306)
Other	0.0321	0.0346	0.0343
	(0.0280)	(0.0279)	(0.0279)
Female	0.0125	0.0131	0.0125
	(0.0095)	(0.0095)	(0.0095)
Married	0.0186	0.0184	0.0195
	(0.0134)	(0.0133)	(0.0133)
Widowed	0.0417	0.0431	0.0430
	(0.0308)	(0.0308)	(0.0308)
Divorced	0.0148	0.0134	0.0140
	(0.0194)	(0.0194)	(0.0194)
Separated	-0.0164	-0.0118	-0.0125
	(0.0291)	(0.0291)	(0.0291)
Partner	-0.0721***	-0.0720***	-0.0726***
	(0.0153)	(0.0153)	(0.0153)
Missing income	-0.0664***	-0.0667***	-0.0660***
	(0.0184)	(0.0184)	(0.0184)
Missing education	0.0307	0.0273	0.0341
	(0.0533)	(0.0533)	(0.0533)
Missing race	-0.0401	-0.0397	-0.0398
	(0.0416)	(0.0416)	(0.0415)
Missing female	0.1488	0.1466	0.1493
	(0.1109)	(0.1108)	(0.1108)
Missing relationship	-0.0517	-0.0515	-0.0523
	(0.0457)	(0.0456)	(0.0456)
Constant	0.8847***	0.8832***	0.8785***

	(0.0383)	(0.0383)	(0.0383)
Observations	10,050	10,050	10,050
R-squared	0.06	0.06	0.06

Standard errors in parentheses; * significant at 10%; ** significant at 5%; *** significant at 1%
Country effects are relative to the United Kingdom, the excluded country variable.

77. Table 20 reports a regression on the use of heated tobacco products, the use of oral nicotine pouches, or the use of both heated tobacco products and oral nicotine pouches, for those respondents that do not smoke cigarettes. The dependent variable is a 0-1 variable for whether the respondent currently uses a heated tobacco product, an oral nicotine pouch product, or both heated tobacco products and oral nicotine pouches and also does not smoke cigarettes. The principal explanatory variable of interest is whether the respondent considers heated tobacco products or oral nicotine pouches to be less harmful. Those who believe heated tobacco products are less harmful than cigarettes are 19% more likely to use a heated tobacco product and not smoke conventional cigarettes. Those who believe oral nicotine pouch products are less harmful than cigarettes are 5% more likely to use an oral nicotine pouch product and not smoke conventional cigarettes

78. In the third regression in Table 20, beliefs regarding whether the product is less harmful than cigarettes are included for both products. In this case, respondents are 15% more likely to be using heated tobacco products or oral nicotine pouches if they perceive heated tobacco products as being less harmful than cigarettes; while the effect of oral nicotine pouch beliefs is not statistically significant once the heated tobacco beliefs variable is included.

Table 20. **Regressions predicting the probability that the respondent CURRENTLY USES product for subsample that DOES NOT SMOKE CIGARETTES, for each or any of two products, based on harm beliefs, country, and demographics**

	Heated yes use	Pouch yes use	Heated or Pouch yes use
Heated less harmful	0.1905***		0.1502***
	(0.0186)		(0.0285)
Pouch less harmful		0.0500***	-0.0390
		(0.0182)	(0.0290)
Belgium	0.4872***	0.4440***	0.5754***
	(0.0443)	(0.0358)	(0.0558)
Denmark	0.0087	-0.0053	0.0499
	(0.0434)	(0.0379)	(0.0604)
Netherlands	0.1335***	0.1453***	0.1360***
	(0.0342)	(0.0329)	(0.0482)
France	0.0820**	0.0616**	0.1377***
	(0.0348)	(0.0303)	(0.0488)
Germany	0.1361***	0.0889***	0.1645***
	(0.0310)	(0.0320)	(0.0463)
Italy	0.2760***	-0.0004	0.3390***
	(0.0301)	(0.0326)	(0.0462)
Age	0.0010	0.0059***	0.0033**
	(0.0010)	(0.0010)	(0.0015)
Age 60+	-0.0073	-0.0785**	0.0659
	(0.0307)	(0.0314)	(0.0460)
Income	0.0030***	0.0029***	0.0042***
	(0.0003)	(0.0003)	(0.0005)
Income €150,000+	-0.0049	0.0885**	-0.1687***
	(0.0448)	(0.0380)	(0.0523)
Years education	0.0040	0.0127***	0.0097
	(0.0043)	(0.0042)	(0.0064)
Black	-0.0604	-0.2043***	-0.0879
	(0.0634)	(0.0495)	(0.0698)
Asian	-0.0785	0.1553**	0.0887
	(0.0805)	(0.0633)	(0.0868)
Other	0.0543	-0.0322	0.1181*
	(0.0624)	(0.0468)	(0.0707)
Female	0.1010***	0.0721***	0.1886***
	(0.0188)	(0.0187)	(0.0282)
Married	0.0090	-0.0511*	-0.0009
	(0.0274)	(0.0285)	(0.0422)
Widowed	-0.0378	-0.0098	-0.0531
	(0.0586)	(0.0578)	(0.0808)
Divorced	0.0646*	-0.0017	0.0789
	(0.0389)	(0.0401)	(0.0571)

Separated	0.0255	0.0858	0.1316
	(0.0560)	(0.0574)	(0.0853)
Partner	0.0484	0.0863***	0.0551
	(0.0304)	(0.0308)	(0.0467)
Missing income	0.1009***	0.0528	0.0714
	(0.0382)	(0.0413)	(0.0663)
Missing education	-0.0283	0.2184*	0.0381
	(0.1199)	(0.1217)	(0.1930)
Missing race	0.0501	0.0836	0.4845***
	(0.0844)	(0.0756)	(0.1288)
Missing female	0.7447**	0.1060	0.6967*
	(0.3717)	(0.2917)	(0.3692)
Missing relationship	0.0809	0.0329	0.0873
	(0.0971)	(0.1004)	(0.1705)
Constant	-0.3044***	-0.5862***	-0.5370***
	(0.0796)	(0.0750)	(0.1163)
Observations	2,063	1,455	1,195
R-squared	0.40	0.61	0.48

Standard errors in parentheses; * significant at 10%; ** significant at 5%; *** significant at 1%
Country effects are relative to the United Kingdom, the excluded country variable.

79. Table 21 and Figures 21A and 21B summarize the reported reasons for not using heated tobacco products and oral nicotine pouches. The most important reason given is that they do not know enough about the products, which is cited by 44% of respondents who had not tried heated tobacco products and by 46% of respondents who had not tried oral nicotine pouches. Belief that the products are not less harmful than regular cigarettes or not believing that the products will be effective in helping the respondent quit smoking are also common responses.

Table 21. **Percentage distribution of the main reason for decision to have NEVER TRIED product for each product**

What is the main reason for you not trying	Heated	Pouch
I do not know enough about them	43.5	45.7
I do not want to quit smoking	8.1	11.8
I do not think that they are any less harmful than cigarettes	17.8	12.3
They cost too much	11.7	6.3
I do not think that they would help me to quit or cut down smoking	12.9	16.6
Other	6.0	7.2
Number of observations	2,685	2,256

Figure 21A. **Main reason given by respondents for never having tried heated tobacco products**

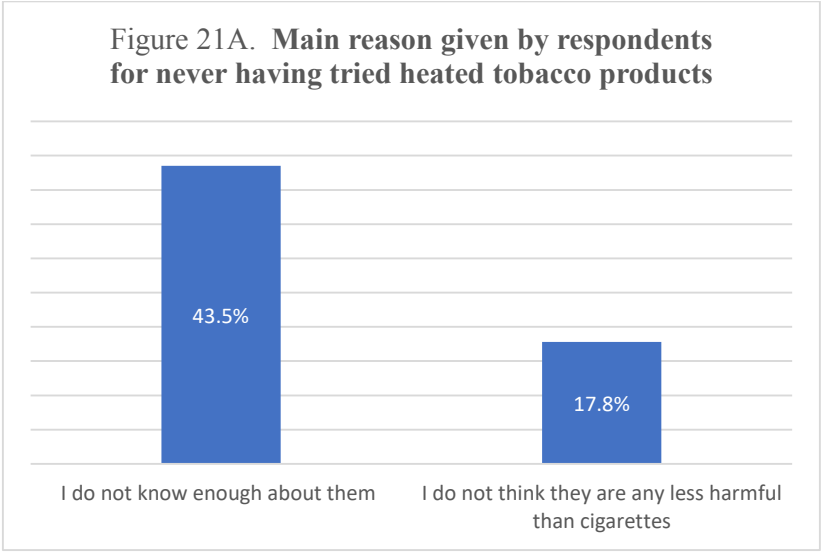
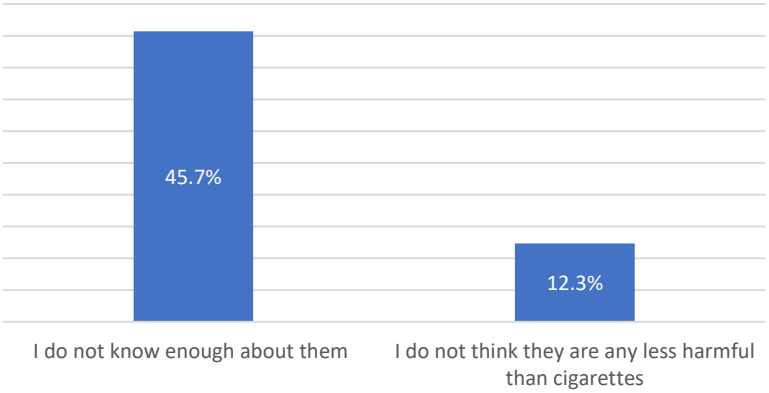


Figure 21B. **Main reason given by respondents for never having tried oral nicotine pouches**



80. The reasons that respondents gave for currently using heated tobacco products and oral nicotine pouches are summarized in Table 22 and Figures 22A and 22B. The dominant response for 58% of heated tobacco users and 70% of pouch users is that the product would help them stop or cut down on their smoking.

Table 22. **Percentage distribution of the main reason for decision to CURRENTLY USE product for each product**

What is the main reason for you using	Heated	Pouch
To help me stop smoking cigarettes	41.1	59.4
To cut down on the amount of cigarettes that I smoke	16.5	11.0
[To help me stop or to cut down]	57.5	70.4
To save money	8.4	7.0
Because they are available in better flavors than cigarettes	12.3	8.2
Convenience, e-cigarettes can be used in more places	11.9	9.6
To not expose people nearby me to cigarette smoke	7.8	4.2
Other	2.1	0.7
Number of observations	1,696	906

Figure 22A. **Main reason for decisions to currently use heated tobacco products**

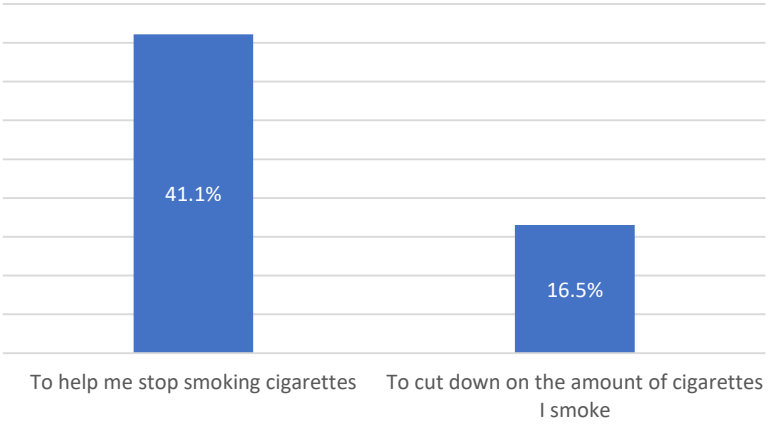
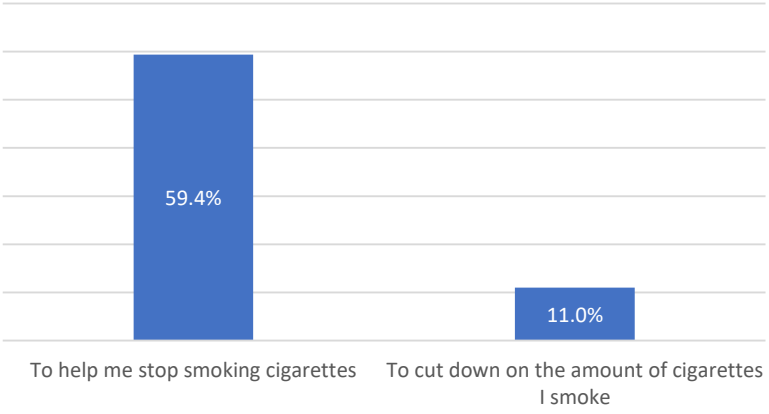


Figure 22B. **Main reason for decisions to currently use oral nicotine pouches**



81. The demographic characteristics of the sample used in the analysis of heated tobacco products and oral pouches are identical to Appendix A, Table Full Sample Characteristics below, since the sample is the same.

VII. COUNTRY-SPECIFIC RESULTS

82. Although a comprehensive discussion of the specific country effects is not included in this report, there are some results that were particularly striking, in addition to the effects of the country variables in the regressions above.

83. The data in Table 23 regarding current product usage and those who do not use cigarettes reflect the influence of the sample screens. The first two columns reflect how respondents were recruited to participate in the survey, where two-thirds were intended to be smokers and two-thirds were intended to be e-cigarette users, with an overlap such that one-third of respondents currently use both cigarettes and e-cigarettes.

84. The last two columns show product usage by country for heated tobacco products and oral nicotine pouches, which were not part of whether the respondent would be included for the sample or screened. As a result of the screening process, the usage of all products in Table 23 is unlikely to be representative of the entire population. Amongst the sample there are significant differences in the use of these products across the different countries.

Table 23. **Percentage who currently use product.**

	Cigarettes	E-Cigarettes	Heated Tobacco Products	Oral Nicotine Pouches
Belgium	66.7	66.7	30.0	28.6
Denmark	74.5	62.7	6.3	3.7
Netherlands	66.7	66.7	16.3	12.4
United Kingdom	66.7	66.7	8.7	4.3
France	66.7	66.7	8.1	4.7
Germany	67.6	66.1	18.8	5.1
Italy	66.7	66.7	26.9	2.7
Total	67.6	66.2	16.9	9.0

85. The distribution of the percentage of those who currently use the product and do not use cigarettes appears in Table 24. The first column again reflects how the sample was recruited, so all respondents who do not currently smoke cigarettes currently use e-cigarettes. In this sample, Belgium and the Netherlands have higher rates of use for heated tobacco products and nicotine pouches. Germany and Italy also have comparatively higher rates of use for heated tobacco products, but this distribution may be a consequence of the sampling procedure.

Table 24. **Percent who currently use product and do not use cigarettes**

	N	E-Cigarettes	Heated Tobacco Products	Oral Nicotine Pouches
Belgium	500	100	60.6	59.6
Denmark	274	100	3.6	1.1
Netherlands	500	100	23.8	20.2
United Kingdom	500	100	3.6	1.0
France	500	100	5.8	2.8
Germany	478	100	15.5	3.8
Italy	500	100	32.2	0.6
Total	3,252	100	22.0	13.6

86. The pivotal measure of risk beliefs is whether the respondent believes that the product is less harmful. This variable is summarized for the different countries in Table 25. The UK and Italy have a comparatively higher proportion of respondents who regard e-cigarettes to be less harmful than cigarettes. Beliefs vary for the other products, but across all countries there is a significant proportion of respondents that do not perceive these products as being less harmful than cigarettes.

Table 25. **Percent who believe product less harmful than cigarettes**

	E-Cigarettes Less Harmful than Cigarettes	Heated Tobacco Products Less Harmful	Oral Nicotine Pouches Less Harmful
Belgium	40.0	61.8	73.5
Denmark	52.0	35.5	43.4
Netherlands	58.5	33.0	37.0
United Kingdom	65.7	41.9	56.0
France	60.0	31.8	39.2
Germany	54.5	39.0	40.8
Italy	65.4	56.8	44.3
Total	56.8	43.6	48.7

87. Table 26 reports for each of the three products, the percentage of current cigarette smokers who believe that the product is the same or more harmful than cigarettes, by country. The perceptions across countries are relatively consistent, where most often at least half of current smokers believe the other products to be as harmful or more harmful compared to cigarettes.

Table 26. **Percent who believe product the same or harmful than cigarettes, current smokers**

	E-Cigarettes Same or More Harmful than Cigarettes	Heated Tobacco Products Same or More Harmful	Oral Nicotine Pouches Same or More Harmful
Belgium	54.9	60.5	41.0
Denmark	59.3	65.0	59.1
Netherlands	53.2	64.2	52.2
United Kingdom	47.7	59.9	48.3
France	53.6	69.6	63.5
Germany	55.8	62.6	60.1
Italy	44.5	48.4	58.4
Total	52.5	60.5	54.6

88. Table 27 reports, for each of the products, the percentage of those who do not use that product who believe that the product is just as harmful or more harmful than cigarettes, by country. A high percentage among non-users of each product regard it as just as

harmful or more harmful than conventional cigarettes. The average across all countries is greater than half for each product. This is the case for each product in every country with the exception of oral nicotine pouches in the United Kingdom.

Table 27. **Percent who believe product same or more harmful than cigarettes, among those who do not currently use the product**

	E-Cigarettes Same or More Harmful than Cigarettes	Heated Tobacco Products Same or More Harmful	Oral Nicotine Pouches Same or More Harmful
Belgium	75.6	77.0	53.9
Denmark	74.8	67.3	57.5
Netherlands	66.6	69.4	63.1
United Kingdom	60.8	59.5	43.9
France	65.6	71.7	60.9
Germany	67.4	66.3	60.4
Italy	57.2	51.7	56.8
Total	66.6	64.5	56.2

89. Table 28 summarizes the country differences in the percentage who give as their reason for not using the product that they do not know enough about the product or they do not think that the product is less harmful. These perceptions are relatively consistent across surveyed countries, where lack of information or a belief that the products are at least as harmful as cigarettes account for between 46% and 71% of respondents' primary reasons for not using the product.

Table 28. **Percent whose main reasons for not using product is do not know enough about them or do not think that they are any less harmful than cigarettes**

	E-Cigarettes	Heated Tobacco Products	Oral Nicotine Pouches
Belgium	56.8	59.5	53.7
Denmark	55.7	59.2	45.7
Netherlands	50.6	62.9	68.1

United Kingdom	49.3	67.9	55.9
France	48.4	67.3	58.9
Germany	58.1	51.9	54.2
Italy	68.1	57.1	70.7
Total	54.3	61.3	58.1

90. The country analyses in the appendices also yielded regression estimates for several key relationships of interest. The coefficients summarized in the first column of Table 29 correspond to the effect of harm beliefs on e-cigarette usage. On average, the belief that e-cigarettes are less harmful than cigarettes increases that the probability of e-cigarette usage by 33%. For all countries, e-cigarette usage is negatively related to being a current smoker, as shown in the second column 2. While the linkage between e-cigarettes being perceived as less harmful than cigarettes and exclusive e-cigarette usage is not statistically significant for the individual countries, it is for the entire sample.

Table 29. **E-cigarettes, comparative country regressions by product use and harm beliefs**

	Table A6	Table A8	Table A9
	E-cigarette less harmful *Predicting* Yes e-cigarette use	E-cigarette yes use *Predicting* Smoker	E-cigarette less harmful *Predicting* Only e-cigarette use
Belgium	0.2864***	-0.3803***	0.0092
Denmark	0.3772***	-0.4181***	-0.0254
Netherlands	0.2955***	-0.4406***	0.0263
United Kingdom	0.3932***	-0.4891***	0.0364
France	0.3514***	-0.4946***	0.0578*
Germany	0.2976***	-0.5034***	0.0082
Italy	0.3182***	-0.5041***	0.0317
Total	0.3260***	-0.4814***	0.0935***

VIII. DISCUSSION

91. Understanding of the attributes of products is an essential input to consumers being able to make efficient decisions with respect to using the product. One such attribute is the potential health risk that the product poses to users of the product. The number of alternative nicotine products on the market has grown to include e-cigarettes, heated tobacco products, and oral nicotine pouches. Available scientific evidence indicates that each of these products offers potential risk reductions as compared to conventional cigarettes. As a result, policies that lead consumers to switch from smoking cigarettes to these products offer potential public health gains.

92. Consumers must make the decision whether to switch from cigarettes to these products. These are individual consumer choices made on a decentralized basis. Understanding of the risks of these alternative products as compared to cigarettes is essential for consumers to make informed decisions with respect to using these alternative products. Understanding of the risk is not only important from the standpoint of potential health consequences but also in terms of matching the product choice to the consumer's preferences.

93. In recognition of the importance of understanding the comparative risks, Public Health England in particular has taken a prominent role in communicating its conclusion that e-cigarettes provide a risk reduction compared to tobacco burning cigarettes of at least 95%.

94. Unfortunately, the available evidence indicates that many consumers have not grasped the extent of the estimated risk reduction provided by alternatives to conventional cigarettes.

95. This study provides new survey results from respondents in seven European countries. The current study provides further evidence, consistent with a number of other studies, that a substantial portion of the public believes that e-cigarettes and other potentially reduced risk nicotine products, are just as harmful or more harmful than cigarettes. This gap in consumer knowledge is consequential, as the results in this report and other studies demonstrate that these risk perceptions are strongly correlated with the non-use of these products. These findings suggest that more needs to be done to improve consumers understanding of the comparative risks of these products.

96. Foregoing consumption of a product that the consumer would choose if adequately informed of the risk of the product, produces a loss for consumers. Consumers would be better off if they understood the potentially lower risks of the alternative products and then made product decisions that matched their preferences. Even if informed of the risk attributes, some consumers may choose to smoke conventional cigarettes than switch to e-cigarettes. But some smokers may be deterred from switching because they do not realize the potential risk reductions that such products offer. These consumers will be worse off than if they had the information to be able to make a more informed choice.

97. The gaps in consumer knowledge, also may lead to a public health loss to the extent that people who would have switched from conventional cigarettes to e-cigarettes or other potentially reduced risk nicotine products are discouraged from doing so because of a misunderstanding of the risks.

98. These misperceptions exist notwithstanding the generally held view by many public health experts and public health authorities that e-cigarettes and other non-combustible tobacco and nicotine products are likely to pose substantially reduced risks compared to

combustible cigarettes. However, some opponents to these products continue to raise concerns regarding the absolute risk of e-cigarettes and the absence of long-term epidemiological evidence regarding these products. A particular example of this approach is that of the World Health Organization (WHO), which emphasizes that e-cigarettes are not safe, and continues to advocate in favor of bans on e-cigarettes, or, if they are not banned, that these products should be regulated in a similar way to traditional tobacco products.[25] The WHO also takes a similar approach to heated tobacco products.[26] However, this approach to communicating the risk of these products, denies current smokers accurate information on the risk of these products compared to cigarettes and contributes to existing misperceptions.

99. Risk perceptions can also be heavily influenced by inaccurate media reporting regarding these products and related research. This misinformation phenomenon was an issue highlighted in the 2018 PHE report, where the authors noted the problem with inaccurate reporting and stated:

> "*The consequences of this inaccurate or inadequate reporting are that the general public is misled. This could induce smokers to carry on smoking rather than switching and EC users to relapse to smoking. While such inaccurate reporting is not confined to the tobacco harm reduction and EC field, the impact is rarely as large. Smoking is uniquely dangerous and each year in England around 80,000 smokers die because of tobacco use (2) . There are few other scientific areas where the gains and losses to public health are so high. It is very likely that these*

[25] See World Health Organization, E-Cigarettes, Q&A, 29 January 2020.
[26] See World Health Organization, Heated tobacco products: a brief (2020).

reports and headlines are playing a key role in the persistent misperceptions that the public have about the relative risks of EC and tobacco cigarettes."[27]

100. A particular example of this is in the case of the reporting of the EVALI cases in the US. While most of the cases in the U.S. have been associated with inhalation of vitamin E acetate, an additive found in some tetrahydrocannabinol ('**THC**') vaping products, news reports often failed to distinguish THC vaping products from standard nicotine-based e-cigarettes.[28] There is some evidence suggesting that this inaccurate reporting has contributed to increasing misperceptions regarding the risk of e-cigarettes.[29]

101. The regulatory regime for these alternative nicotine products is a critical factor for communicating risk and facilitating awareness and trial of these products. Research shows that regulation can affect awareness and use of nicotine vaping products. For example, Gravely, et al (2019) found that:

> "[w]*ith a few exceptions, awareness and use of nicotine vaping products varied by the strength of national regulations governing nicotine vaping product sales/marketing, and by country income" and* "[i]*n contrast to many of the* [less restrictive policies] *and* [restrictive policies] *countries, rates of use were quite low in the* [most restrictive policies] *countries (Australia, Uruguay and Brazil), indicating that strict regulation and enforcement of* [nicotine vaping products]

[27] McNeill A, Brose LS, Calder R, Bauld L & Robson D (2018). Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England, at p173.
[28] See Wayne Hall, Billie Bonevski, Coral Gartner, Policy-based evidence on e-cigarette, or vaping product, use–associated lung injury, Drug and Alcohol Review, 10.1111/dar.13072, **39**, 4, (426-427), (2020).
[29] Tattan-Birch H, Brown J, Shahab L, Jackson SE. Association of the US Outbreak of Vaping-Associated Lung Injury With Perceived Harm of e-Cigarettes Compared With Cigarettes. *JAMA Netw Open.* 2020;3(6):e206981. doi:10.1001/jamanetworkopen.2020.6981.

laws in these countries may have limited smokers' access to these products and/or discouraged smokers from using them".[30]

102. Regulating potentially reduced risk alternative tobacco and nicotine products in the same way as combustible products conveys the message that these products pose the same potential health risks as combustible tobacco products and undermines the communication of the comparative risks of products. The anchoring of the presentation and communication regarding new potentially reduced products with existing more risky products has more general implications for the performance of consumer markets for potentially reduced risk products. If new, potentially reduced risk products become available, these products will encounter the hurdle of overcoming consumers' prior risk beliefs associated with the product class to the extent that consumers are reluctant to alter their high risk beliefs. The dominant market failure may involve overestimation of the new product's riskiness. This influence will impede consumers' response to new, potentially less risky alternative products introduced in the market.

103. For example, requiring e-cigarettes and other potentially reduced risk products to carry the same style warnings and look the same as combustible tobacco products (for example by imposing the same plain or standardized packaging requirements); and applying the same restrictions on product display, will reinforce current beliefs that the risks of these products are comparable in character and magnitude to the risks of cigarettes. The particular challenge for informational policies is to convey the properties of e-cigarettes or and other smoking non-combustible tobacco and nicotine alternatives like heated

[30] Gravely, et al (2019) Prevalence of awareness, ever-use and current use of nicotine vaping products (NVPs) among adult current smokers and ex-smokers in 14 countries with differing regulations on sales and marketing of NVPs: cross-sectional findings from the ITC Project, Addiction. doi: https://doi.org/10.1111/add.14558.

tobacco products and oral nicotine pouches, which are estimated to pose significantly lower health risks than conventional cigarettes but are more comparable in terms of the nicotine levels. Cigarette style warnings and packaging policies are not designed to foster lower risk beliefs with respect to e-cigarettes or to promote accurate comparative risk beliefs. Warnings should frame risk information that allows users to make informed choices.

104. Advertising bans and prohibitions on comparative risk claims prevent manufactures from communicating the attributes of these products and potential benefits for smokers, thereby impeding informed consumer decision making. Imposing advertising bans may also have negative consequences in increasing demand for traditional cigarettes.[31]

IX. CONCLUSION

105. Analysis of the survey results for seven European countries yields differences across countries in terms of the public's perception of alternative nicotine delivery devices. Four conclusions are most noteworthy. First, the perceptions of a substantial segment of the population are not in line with the estimated lower levels of harm posed by e-cigarettes and other non-combustible tobacco and nicotine alternatives like heated tobacco products and oral nicotine pouches, based on prevailing public health opinions. Second, the evidence is strongly consistent with e-cigarettes and other non-combustible tobacco and nicotine products serving as an alternative for conventional cigarettes. Third, the main reasons given by respondents for not using e-cigarettes and other potentially reduced risk products are that they do not know enough about them or they do

[31] See Tuchman, Anna E. 2017. "Advertising and Demand for Addictive Goods: The Effects of E-Cigarette Advertising." Working Paper, Northwestern University Kellogg School of Management

not think that they are less harmful than cigarettes. Fourth, the decisions to use e-cigarettes and other potentially reduced risk products are strongly correlated with perceptions that these products pose less harm than smoking conventional cigarettes, so that continued misperceptions of the estimated harms from non-combustible tobacco and nicotine products have adverse implications for informed consumer decision making.

106. These findings, in combination with the studies reviewed in this report, lead to the following observations and policy recommendations for governments and regulators:

a. The results of the European surveys discussed in this report and other studies, find that consumers are misinformed about the estimated reduced harms of non-combustible tobacco and nicotine products compared to combustible tobacco products.

b. The policy challenge is to address the shortfall in consumer knowledge so that current cigarette smokers can make a comparison between cigarettes and these alternative products that reflects the estimated substantial reduction in the risk of harm that they are expected to provide. Improving the perceptions of harm for non-combustible tobacco and nicotine products in line with their estimated reduced harm compared to conventional cigarettes will likely lead to more smokers switching to these products as an alternative to smoking.

c. To reduce the continued misperception of the estimated harm posed by non-combustible tobacco and nicotine products compared to conventional cigarettes, governments and regulators should treat these products differently than cigarettes and should undertake sustained efforts to communicate the estimated lower risk that they pose compared to cigarettes.

d. Such policies might include efforts along the following lines:

i. Undertaking risk communication efforts that credibly convey to consumers accurate information about the estimated lower risk posed by these non-combustible products.

ii. Adopting warnings for these products that are not patterned on cigarette warnings but rather are reflective of the lower degree of estimated risk that they pose and providing information that facilitates informed consumer decision making. Warnings and other information efforts should not be policies of persuasion designed to discourage smokers' usage of non-combustible tobacco and nicotine products.

iii. Allowing marketing freedoms for companies selling alternative tobacco and nicotine products so that they can create awareness of these products and the estimated risk reduction that they offer to smokers who choose these products instead of cigarettes.

107. The underlying principle of these recommendations, which is that non-combustible tobacco and nicotine products merit quite different treatment than conventional cigarettes, should be carried over across all dimensions of government and regulatory policies. These efforts include, among others, advertising bans and limitations, retail display bans, and requirements regarding the use of plain or standardized packaging as well as restrictions on ingredients and the imposition of taxes. Efforts that adopt the same regulatory approach as is used for tobacco cigarettes will continue to reinforce consumers' misperceptions regarding the comparative estimated risk of these products. There is evidence that consumer beliefs have become more out of line with the estimated

risk that these products pose compared to cigarettes. Given the increase in risk beliefs for e-cigarettes that has been observed in several recent surveys, it is possible that recent regulatory efforts that treat these alternative products in the same way as combustible tobacco products may have even increased the degree of misperception regarding non-combustible tobacco and nicotine products.

W. Kip Viscusi

17 December 2020

Appendix A. Sample Characteristics and Survey Text

Appendix Table Full Sample Characteristics. **Full sample demographic percentages**

Age

	18-20	21-29	30-39	40-49	50-59	60+
Age	2.3	138	27.8	21.6	20.7	13.8

Gender

	Male	Female	Other	No Answer
Gender	52.7	46.4	0.7	0.2

Race or ethnicity

	White	Black	Asian	Multiple	Other	No Answer
Race	91.4	2.2	2.3	2.1	0.6	1.3

Relationship

	Married	Widowed	Divorced	Separated	Never Married	Live-in Partner	No Answer
Relationship	48.6	2.6	8.6	2.8	18.9	17.4	1.1

Education

	Less than High School	High School	Trade / Tech / Vocational	Bachelor	Post-Graduate	No Answer
Education	7.1	25.3	23.4	23.9	19.1	1.1

Income in Euros*

	0-10	10-30	30-49	50-75	75-100	100-125	125-150	150+	No Answer
Income	7.1	25.6	24.3	13.9	10.4	0.7	2.2	7.2	8.6

* United Kingdom and Denmark respondents were adjusted based on their currencies' exchange rate relative to the euro on July 22, 2020 which is the date when half of all surveys were complete. Top income for the United Kingdom is the equivalent of €165,000 or more in pounds. Top income for Denmark is the equivalent €167,500 or more in kroner.

Country

	N	Percentage
Belgium	1,500	14.9
Denmark	1,073	10.7
Netherlands	1,500	14.9
United Kingdom	1,500	14.9
France	1,500	14.9
Germany	1,477	14.7
Italy	1,500	14.9

Anna Dunø Madsen

Fra: Camilla Friborg Madsen
Sendt: 16. marts 2023 14:00
Til: Anna Dunø Madsen
Emne: VS: Høring: Udkast til forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer - intern frist den 24. februar 2023
Vedhæftede filer: Signature-20230207083241.txt

Fra: BOH-FP-Direktion <Direktion.bornholms-hospital@regionh.dk>
Sendt: 7. februar 2023 09:32
Til: Camilla Friborg Madsen <CFMA@SUM.DK>
Emne: VS: Høring: Udkast til forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer - intern frist den 24. februar 2023

Kære Camilla,

På vegne af Bornholms Hospital.

Vi har ingen bemærkninger til fremsendte materiale.

Med venlig hilsen

Tina Munch-Kure
Direktionssekretær

Bornholms Hospital
Direktionen
Ullasvej 8 · DK-3700 Rønne
Dir. tlf. 3867 0020 / Tlf. 3867 0000
tina.munch-kure@regionh.dk
www.bornholmshospital.dk

Fra: Camilla Friborg Madsen <CFMA@SUM.DK>
Sendt: 3. februar 2023 09:26
Til: Advoksamfundet <samfund@advokatsamfundet.dk>; info@alkohologsamfund.dk; ac@ac.dk; ka@ka.dk; Arbejdstilsynet <arbejdstilsynet@at.dk>; Astma-Allergi Forbundet <info@astma-allergi.dk>; Bsinfo@baggersorensen.com; formand@becig.dk; bkd@blaakors.dk; post@branchedanmark.dk; info_dk@bat.com; Danske Læskedrik Fabrikanter (info) <info@bryggeriforeningen.dk>; Børnerådet <brd@brd.dk>; bv@bornsvilkar.dk; kontakt@cfh.ku.dk; forbrugerservice@forbruger.coop.dk; kontakt@dagrofa.dk; Danmarks Apotekerforening <apotekerforeningen@apotekerforeningen.dk>; farmaceutiske-selskab@pharmadanmark.dk; info@lunge.dk; Danmarks Restauranter og Cafeer <drc@thehost.dk>; da@da.dk; formand@dadafo.dk; Dansk Erhverv (info) <info@danskerhverv.dk>; Emballageindustrien <hoering@di.dk>; dls.dlsoffice@gmail.com; Helen Gerdrup Nielsen <Helen.Gerdrup.Nielsen@regionh.dk>; dsam@dsam.dk; RHP-ADM - Region Hovedstadens Psykiatri <psykiatri@regionh.dk>; administration@dsff.dk; info@patientsikkerhed.dk; support@bilka.dk; dsr@dsr.dk; Dansk Transport og Logistik (DTL) <dtl@dtl.eu>; fysio@fysio.dk; kontakt@dgsnet.dk; dh@handicap.dk; info@danskepatienter.dk; Danske Regioner <regioner@regioner.dk>; info@danske-seniorer.dk; dse@skoleelever.dk; info@dansktp.dk; info@danske-aeldreraad.dk; Post@dataetiskraad.dk; Datatilsynet <dt@datatilsynet.dk>; dsk@dsk.dk; dommerforeningen@gmail.com; Det Etiske Råd kontakt <kontakt@etiskraad.dk>; Diabetesforeningen <info@diabetes.dk>; sales@efuma.com; kontakt@eeo.dk; foa@foa.dk; fh@fho.dk; hero@fho.dk; bla@fho.dk; EUI@fho.dk; Faglig Fælles Forbund 3F <3f@3f.dk>;

ff@farmakonom.dk; fa@fanet.dk; 1 - KFST Forbrugerombudsmanden (KFST) <FO@Forbrugerombudsmanden.dk>; 1 - KFST Forbrugerombudsmanden (KFST) <FO@Forbrugerombudsmanden.dk>; Forbrugerrådet <hoeringer@fbr.dk>; hf@fadl.dk; fas@dadl.dk; kontakt@fdih.dk; info@fpmdk.dk; hs@fpmdk.dk; fp@fogp.dk; mal@fogp.dk; himr@himr.fo; Gigtforeningen <info@gigtforeningen.dk>; Hjerteforeningen <post@hjerteforeningen.dk>; horesta@horesta.dk; info@oliver-twist.dk; oliver-twist@oliver-twist.dk; info@igldk.dk; info.dk@jti.com; sek@jordemoderforeningen.dk; national@kfum-kfuk.dk; kk@kirkenskorshaer.dk; kfs@sundkom.dk; Kommunernes Landsforening <KL@KL.DK>; Kræftens Bekæmpelse <info@cancer.dk>; los@los.dk; lh@handelselever.dk; lo@lo.dk; Lægeforeningen <dadl@dadl.dk>; Brancheforeningen for Lægemiddelvirksomheder i Danmark (LIF) <info@lif.dk>; medico@medicoindustrien.dk; ungdom@danskmetal.dk; cach@danskmetal.dk; moedrehjaelpen@moedrehjaelpen.dk; govsec@nanoq.gl; NVK Kontakt <kontakt@nvk.dk>; DKetik Institutionspostkasse <DKetik@DKetik.dk>; isf@nikotinbranchen.dk; Nærbutikkernes Landsforening <info@nbl-landsforening.dk>; nnf@nnf.dk; Offentligt Ansattea Organisationer <oao@oao.dk>; info@pfldk.dk; medlem@patientforeningen.dk; njl@patientforeningen.dk; info@patientforeningen-danmark.dk; pd@pharmadanmark.dk; info@pharmakon.dk; christoffer.arzrouni@pmi.com; Pmaps@pmi.com; plo@dadl.dk; pto@pto.dk; info@rigsrevisionen.dk; kontakt@roegfrifremtid.dk; Rådet for Socialt Udsatte <post@udsatte.dk>; post@skole-foraeldre.dk; Jeanett@SMOKE-IT.dk; Jens@SMOKE-IT.dk; support@gejser.dk; info@smokesolution.com; benny.husted@ssp-samraadet.dk; post@sundbynetvaerket.dk; info@sundheddanmark.nu; shk@sundhedskartellet.dk; silkeborg@swedishmatch.com; info@sygeforsikring.dk; info@tandlaegeforeningen.dk; jh@tobaksindustrien.dk; info@tobaksproducenterne.dk; info@vinordic.org; aeldresagen@aeldresagen.dk; yl@dadl.dk
Emne: Høring: Udkast til forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer

Til alle høringsparter

Se venligst vedhæftede høring over udkast til forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer (Implementering af dele af delegeret direktiv vedrørende opvarmede tobaksvarer samt andre præciseringer og tekniske justeringer)

Indenrigs- og Sundhedsministeriet skal anmode om at modtage eventuelle bemærkninger til udkastet **senest mandag d. 6. marts 2023 kl. 12.**

Bemærkninger bedes sendt til sum@sum.dk og til cfma@sum.dk.

Camilla Friborg Madsen
Fuldmægtig, Kontor for Forebyggelse og Strålebestyttelse
M 21 67 75 18
@ cfma@sum.dk

INDENRIGS- OG SUNDHEDSMINISTERIET

Indenrigs- og Sundhedsministeriet
Tlf. 7226 9000

Bryggeriforeningen
Danish Brewers' Association

Indenrigs- og Sundhedsministeriet
Sagsnummer 2213653
sum@sum.dk
cfma@sum.dk

Den 6. marts 2023

Høring over udkast til forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer

Bryggeriforeningen takker for muligheden for at afgive bemærkninger til lovforslaget.

Bryggeriforeningens bemærkninger vedrører den del af lovforslaget, der præciserer kravene til alderskontrol.

I høringsbrevet er det oplyst, at der i forbindelse med flere domstolsprøvelser ikke er tilstrækkelig klar lovhjemmel til at stille krav om, at erhvervsdrivende skal etablere et generelt alderskontrolsystem ved online salg af varer underlagt salgsaldersgrænse. Det er i tilknytning hertil Bryggeriforeningens vurdering, at det er essentielt, at lovgivningen virker, hvilket bl.a. betyder, at lovhjemmelen skal være tilstrækkelig ved domstolsprøvelser.

Det er vigtigt og relevant, at der med det konkrete lovforslag implementeres en effektiv lovhjemmel, der kan sikre optimale domstolsprøvelser, men den eksisterende udfordring med håndhævelsen af salgsaldersgrænserne bør også søges løst.

Håndhævelsen af salgsaldersgrænserne har i mange år været en stor udfordring, hvilket afspejles i en række undersøgelser fra Sundhedsstyrelsen m.fl. Grunden til at håndhævelsen ikke fungerer i praksis i den fysiske handel kan sandsynligvis henføres til, at det alene er den enkelte kassemedarbejder, der er ansvarlig for at vurdere kundens alder, hvilket resulterer i mange fejl. For så vidt angår online håndhævelse er det nærliggende, at grunden primært skyldes muligheden for omgåelse. Sådan som løsningen er i dag ved online salg, kan mindreårige i de fleste situationer indtaste en hvilken som helst alder ved køb af varer (pop up, afkrydsning eller andet), der er underlagt salgsaldersgrænse.

Som en del af løsningen på den mangeårige håndhævelsesudfordring foreslår Bryggeriforeningen, at Sundhedsministeriet nedsætter arbejdsgruppe, der skal afsøge hvilke tilgængelige løsninger for alderskontrol, der i væsentligt og tilfredsstillende omfang kan forbedre håndhævelsen af de nuværende salgsaldersgrænser. Dette arbejde kan f.eks. ske i forlængelse af de drøftelser som Sundhedsministeriet igangsatte i foråret 2022 med deltagelse af en række organisationer. Som repræsentant for bryggerierne deltager Bryggeriforeningen gerne i dette videre arbejde.

Det er Bryggeriforeningens vurdering, at der er behov for at få udviklet et digitalt alderskontrolsystem, der kan sikre en forbedring af såvel håndhævelsen i den fysiske detailhandel som ved online salg. Et digitalt alderskontrolsystem skal forhindre, at kunder kan gennemføre køb af produkter, som de ikke er gamle nok til at købe.

Bryggeriforeningen / Danish Brewers' Association
Faxehus, Gamle Carlseberg Vej 16, DK-2500 Valby
Tel. +45 72 16 24 24
info@bryggeriforeningen.dk
www.bryggeriforeningen.dk

Et digitalt alderskontrolsystem kræver udvikling af en løsning, der ikke er tilgængelig i dag, men som ifølge flere af de relevante og naturligt involverede parter, herunder også fx MasterCard, er realistisk, da der til hvert elektroniske betalingsmiddel er knyttet en konkret kontohaver. Ved at indhente samtykke fra kontohaver med accept til at foretage alderskontrol, er det muligt digitalt at verificere alderen ved køb i detailhandlen, når forbrugeren gennemfører sin betaling elektronisk, hvad enten det er med kort eller telefon ved terminalen – såvel fysisk som online.

Giver høringssvaret anledning til spørgsmål, står vi naturligvis til rådighed.

Med venlig hilsen

Lea Kholghi Frederiksen
Erhvervspolitisk chef

Mobil (+45) 29 27 26 23
lkf@bryggeriforeningen.dk

BRYGGERIFORENINGEN
Danish Brewers' Association
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Indenrigs- og Sundhedsministeriet
Att.: Camilla Friborg Madsen

Den 6. marts 2023

Høring: udkast til forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfrie miljøer

Dansk Erhverv har modtaget ovenstående udkast til lovforslag i høring. Lovforslaget gennemfører dele af delegeret direktiv vedrørende opvarmede tobaksvarer samt en præcisering af lovgivning vedr. alderskontrol og skiltning, som baserer sig på eksisterende praksis på området og med formålet at skabe lovhjemmel for, at erhvervsdrivende kan pålægges straf, såfremt de ikke overholder kravene. Dansk Erhverv har følgende bemærkninger til udkastet:

Generelle bemærkninger
Dansk Erhverv støtter formålet med forslaget og deler ønsket om at sætte ind mod unges rygning. Dansk Erhverv er medlem af partnerskabet for Røgfri fremtid.

For så vidt angår første del af lovforslaget vedrørende gennemførelse af dele af delegeret direktiv om opvarmede tobaksvarer, bakker Dansk Erhverv op om forslaget, der vurderes at kunne bidrage til at begrænse forbruget af de opvarmede tobaksprodukter.

Ligeledes bakker Dansk Erhverv op om lovforslagets præcisering af lovgivning vedrørende alderskontrol og skiltning, da denne præcisering allerede er eksisterende praksis og alene har til formål at skabe tilstrækkelig lovhjemmel.

Metode til alderskontrol ved online salg

Dansk Erhverv noterer sig, at der i lovforslaget fortsat er lagt op til metodefrihed for alderskontrol ved online salg (pop up, afkrydsning eller andet). Dette bakker Dansk Erhverv fuldt op om og det vil også fremadrettet være et opmærksomhedspunkt for Dansk Erhverv, da vi mener, det er vigtigt, at de erhvervsdrivende ikke bebyrdes med krav til specifikke metoder til alderskontrol mv.

Med venlig hilsen,

Stine Sjølund Blok
Chefkonsulent

stsb@danskerhverv.dk
stsb/STSB

Indenrigs- og Sundhedsministeriet

Fremsendt pr. e-mail til sum@sum.dk og cfma@sum.dk

28. februar 2023

Høringssvar fra Dansk Selskab for Folkesundhed vedr.:

"Lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer"

DSFF hilser det meget velkommen at **opvarmede tobaksvarer** fremover ikke kan undtages fra bestemmelserne i artikel 7, stk. 1 og 7. DSFF støtter fuldt ud op om at det skal være forbudt at markedsføre opvarmede tobaksvarer med en kendetegnende aroma, og at det skal være forbudt at markedsføre opvarmede tobaksvarer, der indeholder aromastoffer i deres bestanddele såsom filtre, papir, emballage, kapsler eller enhver teknisk funktion, der gør det muligt at ændre opvarmede tobaksvarers duft eller smag eller deres røgudviklingsintensitet. DSFF støtter også at opvarmede tobaksvarer, der består af filtre, papir eller kapsler med indhold af tobak eller nikotin, ikke må markedsføres her i landet og at opvarmede tobaksvarer skal have samme kombinerede sundhedsadvarsler som cigaretter.

DSFF finder det meget vigtigt, at smagsstoffer ikke kun forbydes som **"kendetegnende aromaer"**, men som ingredienser, så der ikke er tvivl om, hvor meget smag, der må/ikke må tilsættes et produkt. DSFF vil dog gerne opponere imod at opvarmet tobak fremover kun vil være omfattet af bestemmelserne i artikel 7, stk. 1 og 7, i tobaksvaredirektivet *for så vidt opvarmet tobak er røgtobak.*

DSFF vil gerne opponere imod at opvarmet tobak både kan defineres som røgtobak og røgfri tobak jf. følgende definition af opvarmet tobak:

I *§ 2* indsættes som *nr. 31*: »31) Opvarmet tobaksvare: En ny kategori af tobaksvarer, der opvarmes for at frembringe en emission indeholdende nikotin og andre kemikalier,
som derefter inhaleres af brugeren/brugerne, og *som afhængigt af deres karakteristika*
er røgfrie tobaksvarer eller røgtobak. «

Udtrykket "som afhængigt af deres karakteristika er røgfrie tobaksvarer eller røgtobak" er yderst uheldig, da det ikke specificeres hvad der menes med karakteristika. Denne unøjagtige formulering vil uden tvivl blive udnyttet af tobaksproducenterne, der har en stærk interesse i at markedsføre opvarmet tobak som et "uskadeligt alternativ" til almindelige cigaretter. De amerikanske sundhedsmyndigheder, FDA, har konkluderet "data failed to show consistently lower risks of harm in humans using IQOS (et opvarmet tobaksprodukt) compared with conventional cigarettes." WHO anbefaler at opvarmet tobak lovgives som andre tobaksvarer. Opvarmet tobak er små cigaretter lavet af tobaksblade, og udover at være stærkt afhængighedsskabende, dannes der mange stærkt sundhedsskadelige stoffer ved opvarmning. Det bør ikke være til forhandling om tobak er tobak, uanset om det opvarmes, puttes under læben, brændes eller indtages på anden vis.

DSFF anbefaler derfor at al opvarmet tobak fremover defineres som røgtobak og at al opvarmet tobak således fremover vil være omfattet af bestemmelserne i artikel 7, stk. 1 og 7 i tobaksvaredirektivet.

DSFF hilser det meget velkommen at pligten til at drive et alderskontrolsystem fremover vil påhvile alle detailforhandlere af tobaksvarer, tobakssurrogater og urtebaserede rygeprodukter, der markedsfører via fjernsalg, og ikke kun dem, der markedsfører via fjernslag over landegrænser. Ved markedsføring af produkterne online foreslås det, at der skal etableres og drives et generelt alderskontrolsystem. Dette skal bl.a. gøres via en app-funktion, for at sikre et system, der effektivt verificerer køberens alder.

Når man læser lovteksten, fremstår den dog ikke så stærk som ønsket.
Stk. 3. Den, der erhvervsmæssigt markedsfører elektroniske cigaretter eller genopfyldnings-beholdere med eller uden nikotin online, skal kræve, at *kunden inden salget gennemføres utvetydigt tilkendegiver, om kunden er fyldt 18 år*.«
Ansvaret lægges altså hos kunden, ikke den erhvervsdrivende. Når en 15-årig ønsker at købe tobak eller e-cigaretter online skal vedkommende så bare sætte et hak ved "ja, jeg er over 18 år"? Dette har i DSFFs øjne intet med alderskontrol at gøre. Det svarer til at man i fysiske butikker bare skal nikke ja til at man er over 18 år, uden legitimation. Unge, kan med få klik få tilsendt store mængder tobak/tobakssurrogater via onlinekøb. DSFF opponerer stærkt imod dette. Som udgangspunkt mener DSFF, ligesom WHO, at online salg af tobak og tobakssurrogater ikke skal være tilladt. Såfremt denne anbefaling fra WHO ikke følges, vil vi opfordre til at man strammer lovteksten, så onlinesalg af tobaksprodukter og tobakssurrogater kun kan finde sted ved brug af fx MitID, så der sikres en reel alderskontrol. DSFF anbefaler at man suspenderer muligheden for at forhandle tobaksvarer indtil en tilfredsstillende og sikker løsning vedr. alderskontrol er etableret.

DSFF vil til sidst gerne gøre opmærksom på at vi er meget uenige i tobaksvaredirektivets artikel 7, stk. 12, hvor det fremgår, at andre tobaksvarer end cigaretter og rulletobak er undtaget fra forbuddene i stk. 1 og 7. Disse undtagelser er allerede blevet udnyttet at tobaksproducenterne. I USA sælges små cigarer der til forveksling ligner almindelige cigaretter, men har brunt rullepapir. De sælges med søde smagsstoffer, de sælges i farvestrålende pakninger, der reklameres kraftigt for dem, og de ligger ved kassen i børns øjenhøjde – fordi de kan omgå tobaksvarelovgivningen. Flere unge i USA bruger små cigarer end almindelige cigaretter.

På vegne af Dansk Selskab for Folkesundhed

Helle Terkildsen Maindal
Forperson

Nina Krogh Larsen
Bestyrelsessuppleant

Indenrigs- og Sundhedsministeriet
Holbergsgade 6
1057 København K

E-mail: sum@sum.dk, cc: cfma@sum.dk

Høringssvar vedr. udkast til forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer (Implementering af dele af delegeret direktiv vedrørende opvarmede tobaksvarer samt andre præciseringer og tekniske justeringer)

Dato:
6. marts 2023

Danske Patienter
Kompagnistræde 22, 1. sal
1208 København K

Tlf.: 33 41 47 60

www.danskepatienter.dk

E-mail:
lk@danskepatienter.dk

Cvr-nr: 31812976

Danske Patienter takker for muligheden for at afgive høringssvar til det fremsendte lovforslag. I Danmark er der mange børn og unge, der begynder at ryge og bliver afhængige af nikotin – og det sker i takt med, at der kommer flere og flere tobaks- og nikotinprodukter på markedet. I Danske Patienter bakker vi derfor op om øget regulering af opvarmede tobaksvarer.

Danske Patienter mener, at opvarmede tobaksvarer skal reguleres på linje med cigaretter og anden tobak. Vi er derfor positive over for, at der lægges op til, at opvarmede tobaksvarer omfattes af samme forbud mod aromastoffer som cigaretter. Mentol og andre aromaer gør produkterne mere tiltrækkende for særligt børn og unge og bør derfor forbydes i opvarmede tobaksvarer. Vi mener desuden, at forbuddet mod aromastoffer bør udvides til at gælde for alle typer af tobaksvarer.

Vi finder det også positivt, at der indføres lovhjemmel til at stille krav om alderskontrol ved online salg af tobak, urtebaserede rygeprodukter, tobakssurrogater og e-cigaretter. Vi frygter dog, at det i sig selv ikke er tilstrækkeligt, idet forhandlere blot kan vælge at lade forbrugere krydse af, at de er over 18 år. Vi mener derfor, at det er mere oplagt helt at forbyde salg af tobak og lignende produkter online, hvilket WHO ligeledes anbefaler. Det mener vi vil gøre tobak mindre tilgængeligt for særligt børn og unge.

Med venlig hilsen

Morten Freil
Direktør

NOTAT

Danske Regioners bemærkninger til høring af Udkast til forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer

21-02-2023
EMN-2023-00263
1610034
Sofie Vennike

Indenrigs- og Sundhedsministeriet har d. 3. februar 2023 anmodet om Danske Regioners bemærkninger til lovforslag vedrørende lov om tobaksvarer og alkohol.

Med lovforslaget udvides forbuddet mod markedsføring af tobaksvarer nu til også at omfatte opvarmede tobaksvarer. Lovforslaget skal gøre opvarmede tobaksvarer mindre attraktive, og gøre forbrugere mere opmærksomme på de sundhedsrisici, der er forbundet med at anvende opvarmede røgtobaksvarer. Direktivet forventes således at bidrage til at begrænse forbruget af opvarmede tobaksvarer, herunder at børn og unge indleder et forbrug. Lovforslaget har til formål at rette op på, at der ikke er tilstrækkelig klar lovhjemmel til at stille krav om, at erhvervsdrivende skal etablere et generelt alderskontrolsystem ved online salg af disse produkter.

Danske Regioner går ind for en målrettet og koordineret forebyggende indsats på tobaks- og alkoholområdet, og på den baggrund bakker Danske Regioner derfor op om lovforslaget.

På vegne af Danske Regioner

Thomas I. Jensen

Indenrigs- og Sundhedsministeriet
E-mail: sum@sum.dk og cfma@sum.dk.

23. februar 2023

Danske Tandplejere
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Høringssvar vedr. Udkast til forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer

Danske Tandplejere takker for muligheden for at komme med bemærkninger til ovennævnte høring.

Danske Tandplejere støtter generelt op om alle tiltag og lovændringer, som mindsker brugen af nikotinholdige produkter af alle slags, da nikotin og indtaget heraf har en yderst skadelig effekt på borgerens generelle sundhed, herunder også borgernes tandsundhed. Der er blandt andet en markant og signifikant sammenhæng mellem parodontitis og brug af tobaksprodukter. Parodontitis udvikler sig hurtigere hos rygere, og succesraten ved behandling er langt ringere hos rygere end hos ikke-rygere. Disse helbredsmæssige konsekvenser er også gældende for børn og unge, der bruger tobaks- og nikotinholdige produkter, hvor eksempelvis brugen af snusprodukter har fået antallet af skader på tandkød og den generelle mundsundhed til at udvikle sig negativt for et stort antal børn og unge.

Danske Tandplejere støtter derfor op om de foreslåede lovændringer og står naturligvis til rådighed, hvis ovenstående ønskes uddybet.

Venlig hilsen,

Elisabeth Gregersen

Formand, Danske Tandplejere

DSK

Indenrigs- og Sundhedsministeriet
Sagsnummer 2213653
sum@sum.dk
cfma@sum.dk

København, den 21. februar 2023

Høring over udkast til forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer

De Samvirkende Købmænd, DSK, har den 3. februar 2023 modtaget ovennævnte forslag i høring.

Medlemskredsen omfatter godt 1.500 supermarkeder, discountbutikker, nærbutikker og convenience. DSK har også samtidig et tæt samarbejde med de to grossister i den frie sektor: Dagrofa og Reitan Distribution. DSK's medlemmer beskæftiger samlet set ca. 35.000 ansatte.

Vi takker for muligheden for at afgive kommentarer.

DSK har alene bemærkninger til den del af lovforslaget, der omhandler alderskontrol i fysiske butikker. Alderskontrol i de fysiske butikker er baseret på, at der skal kræves billedlegitimation, hvis sælgeren er i tvivl om, hvorvidt kunden er fyldt 16 år hhv. 18 år afhængig af den pågældende vare.

I praksis er det alene den enkelte kassemedarbejder, der vurderer kundens alder og det medfører for mange fejl, hvor for unge kunder køber varer som de ellers ikke bør.

En undersøgelse fra HK Handel 2022 viser, at hele 80% af de adspurgte butiksansatte har oplevet at blive talt grimt eller nedsættende til af kunder. Når kunderne ikke i tilstrækkelig grad respekterer, at de butiksansatte varetager en jobfunktion med at sikre overholdelse af lovgivning, får de butiksansatte ikke altid bedt om fremvisning af gyldig billedlegitimation.

Det afspejles da også i adskillige undersøgelser – herunder branchens egne - der konkluderer, at det lykkes for en stor andel unge at købe alkohol og tobak mv., som de ikke er gamle nok til at købe.

Det skal der rettes op på. De politisk fastsatte aldersgrænser skal naturligvis overholdes.

Hos DSK vil vi gerne opfordre til, at der udarbejdes et alderskontrolsystem, der ikke kun skal benyttes ved fjernsalg, men som også kan benyttes ved fysisk handel.

I Danmark er vi rigtig gode til brug af nye IT-løsninger. Danmark er faktisk blandt de mest digitaliserede lande i verden. Det bør vi udnytte ved alderskontrollen, så effektiviteten af lovgivningen ikke alene afhænger af kassemedarbejderens vurdering, når den butiksansatte er face-to-face med forbrugeren.

Der er endnu ikke udviklet en 100% effektiv digital løsning, men det er vigtigt, at "hullerne i osten" ikke længere får lov til at skygge for de fremskridt som brugen af teknologi kan medvirke til.

Digital alderskontrol kan f.eks. ske automatisk, når forbrugeren gennemfører sin betaling elektronisk, hvad enten det er med kort eller telefon ved terminalen. Stregkoden på varen fortæller, hvis varen er underlagt en salgsaldersgrænse, og hvis forbrugeren ikke er gammel nok til at købe varen, bliver betalingen automatisk afvist.

Det kræver udvikling af en løsning, der ikke er tilgængelig i dag, men som bør være realistisk, da hvert eneste elektroniske betalingsmiddel er knyttet til en konkret kontohaver.

En digitaliseret løsning bør godkendes af Datatilsynet inden den lanceres. Der må på ingen som helst måde skabes tvivl om forbrugerbeskyttelsen og en digitaliseret løsning bør udelukkende forholde sig til, hvorvidt kunden er gammel nok. Ja eller nej.

Prissætningen – en elektronisk løsning vil ikke være gratis - bør vurderes af Konkurrence- og Forbrugerstyrelsen på lige fod med f.eks. styrelsens overvågning af prissætningen på Dankortet.

Andre digitaliserede kontrolmuligheder end via betalingsmidlet bør ikke udelukkes på forhånd.

Visionen må være, at der tilvejebringes et effektivt alderskontrolsystem, der ikke kun finder anvendelse ved markedsføring via fjernsalg, men ligeledes ved fysisk handel. Løsningen er ikke tilgængelig i dag, men arbejdet bør igangsættes hurtigst muligt under politisk ledelse.

På den baggrund vil vi opfordre til, at der gøres et helhjertet forsøg på at forene såvel dagligvarehandlen, de butiksansatte, producenterne af de berørte varer, NGO'ere med naturlig interesse for børn og unges sundhed samt den finansielle sektor til drøftelser om, hvordan alderskontrollen i de fysiske butikker kan forbedres mærkbart ved brug af en form for digitaliseret løsning.

Supplerende forslag, der skal medvirke til øget beskyttelse af børn og unge:

- Ved handel online, skal kunden inden salget gennemføres utvetydigt tilkendegive, om kunden er fyldt 16 år hhv. 18 år. En lignende løsning bør tænkes ind i den fysiske handel. Her kan man f.eks. forestille sig, at det ikke kun er forbudt at sælge til for unge kunder - det krav skal naturligvis fortsat gælde – men at det også bliver forbudt at erhverve sig produkter med salgsaldersgrænse, hvis man som kunde ikke er gammel nok. Købsforbuddet foreslås markedsført med krav om tydelig skiltning, så unge overtræder købsforbuddet, hvis salgsstedet efterlever krav om tydelig skiltning efter myndighedernes anvisning.

- Der bør indføres et forbud mod såkaldt proxysalg, så man fremadrettet kan få en bøde, hvis man for eksempel køber tobak eller alkohol på vegne af en mindreårig, hvor der er sket en økonomisk transaktion, hvor den myndige tager betaling for at købe tobak eller alkohol mv på vegne af den mindreårige.

Giver vores høringssvar anledning til yderligere, er vi naturligvis til rådighed.

Med venlig hilsen

Claus Bøgelund Nielsen
Vicedirektør

Anna Dunø Madsen

Fra: David Luxhøj-Pedersen <dlp@fanet.dk>
Sendt: 9. februar 2023 12:19
Til: Camilla Friborg Madsen; DEP Sundhedsministeriet
Emne: SV: Høring: Udkast til forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer
Vedhæftede filer: Signature-20230209111926.txt

Kære Camilla

Finanssektorens Arbejdsgiverforening (FA) takker for høringsmuligheden og har ingen bemærkninger til lovforslagene.

Med venlig hilsen

David Luxhøj-Pedersen
Advokatfuldmægtig

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1256 København K

FA FINANSSEKTORENS ARBEJDSGIVERFORENING

Fra: Camilla Friborg Madsen <CFMA@SUM.DK>
Sendt: 3. februar 2023 09:26
Til: Advoksamfundet <samfund@advokatsamfundet.dk>; info@alkohologsamfund.dk; ac@ac.dk; ka@ka.dk; Arbejdstilsynet <arbejdstilsynet@at.dk>; Astma-Allergi Forbundet <info@astma-allergi.dk>; Bsinfo@baggersorensen.com; formand@becig.dk; bkd@blaakors.dk; post@branchedanmark.dk; info_dk@bat.com; Danske Læskedrik Fabrikanter (info) <info@bryggeriforeningen.dk>; Børnerådet <brd@brd.dk>; bv@bornsvilkar.dk; kontakt@cfh.ku.dk; forbrugerservice@forbruger.coop.dk; kontakt@dagrofa.dk; Danmarks Apotekerforening <apotekerforeningen@apotekerforeningen.dk>; farmaceutiske-selskab@pharmadanmark.dk; info@lunge.dk; Danmarks Restauranter og Cafeer <drc@thehost.dk>; da@da.dk; formand@dadafo.dk; Dansk Erhverv (info) <info@danskerhverv.dk>; Emballageindustrien <hoering@di.dk>; dls.dlsoffice@gmail.com; Helen.gerdrup.nielsen@regionh.dk; dsam@dsam.dk; psykiatri@regionh.dk; administration@dsff.dk; info@patientsikkerhed.dk; support@bilka.dk; dsr@dsr.dk; Dansk Transport og Logistik (DTL) <dtl@dtl.eu>; fysio@fysio.dk; kontakt@dgsnet.dk; dh@handicap.dk; info@danskepatienter.dk; Danske Regioner <regioner@regioner.dk>; info@danske-seniorer.dk; dse@skoleelever.dk; info@dansktp.dk; info@danske-aeldreraad.dk; Post@dataetiskraad.dk; Datatilsynet <dt@datatilsynet.dk>; dsk@dsk.dk; dommerforeningen@gmail.com; Det Etiske Råd kontakt <kontakt@etiskraad.dk>; Diabetesforeningen <info@diabetes.dk>; sales@efuma.com; kontakt@eeo.dk; foa@foa.dk; fh@fho.dk; hero@fho.dk; bla@fho.dk; EUI@fho.dk; Faglig Fælles Forbund 3F <3f@3f.dk>; ff@farmakonom.dk; Finanssektorens Arbejdsgiverforening <fa@fanet.dk>; 1 - KFST Forbrugerombudsmanden (KFST) <FO@Forbrugerombudsmanden.dk>; 1 - KFST Forbrugerombudsmanden (KFST) <FO@Forbrugerombudsmanden.dk>; Forbrugerrådet <hoeringer@fbr.dk>; hf@fadl.dk; fas@dadl.dk; kontakt@fdih.dk; info@fpmdk.dk; hs@fpmdk.dk; fp@fogp.dk; mal@fogp.dk; himr@himr.fo; Gigtforeningen <info@gigtforeningen.dk>; Hjerteforeningen <post@hjerteforeningen.dk>;

horesta@horesta.dk; info@oliver-twist.dk; oliver-twist@oliver-twist.dk; info@igldk.dk; info.dk@jti.com; sek@jordemoderforeningen.dk; national@kfum-kfuk.dk; kk@kirkenskorshaer.dk; kfs@sundkom.dk; Kommunernes Landsforening <KL@KL.DK>; Kræftens Bekæmpelse <info@cancer.dk>; los@los.dk; lh@handelselever.dk; lo@lo.dk; Lægeforeningen <dadl@dadl.dk>; Brancheforeningen for Lægemiddelvirksomheder i Danmark (LIF) <info@lif.dk>; medico@medicoindustrien.dk; ungdom@danskmetal.dk; cach@danskmetal.dk; moedrehjaelpen@moedrehjaelpen.dk; govsec@nanoq.gl; NVK Kontakt <kontakt@nvk.dk>; DKetik Institutionspostkasse <DKetik@DKetik.dk>; isf@nikotinbranchen.dk; Nærbutikkernes Landsforening <info@nbl-landsforening.dk>; nnf@nnf.dk; Offentligt Ansattea Organisationer <oao@oao.dk>; info@pfldk.dk; medlem@patientforeningen.dk; njl@patientforeningen.dk; info@patientforeningen-danmark.dk; pd@pharmadanmark.dk; info@pharmakon.dk; christoffer.arzrouni@pmi.com; Pmaps@pmi.com; plo@dadl.dk; pto@pto.dk; info@rigsrevisionen.dk; kontakt@roegfrifremtid.dk; Rådet for Socialt Udsatte <post@udsatte.dk>; post@skole-foraeldre.dk; Jeanett@SMOKE-IT.dk; Jens@SMOKE-IT.dk; support@gejser.dk; info@smokesolution.com; benny.husted@ssp-samraadet.dk; post@sundbynetvaerket.dk; info@sundheddanmark.nu; shk@sundhedskartellet.dk; silkeborg@swedishmatch.com; info@sygeforsikring.dk; info@tandlaegeforeningen.dk; jh@tobaksindustrien.dk; info@tobaksproducenterne.dk; info@vinordic.org; aeldresagen@aeldresagen.dk; yl@dadl.dk
Emne: Høring: Udkast til forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer

Til alle høringsparter

Se venligst vedhæftede høring over udkast til forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer (Implementering af dele af delegeret direktiv vedrørende opvarmede tobaksvarer samt andre præciseringer og tekniske justeringer)

Indenrigs- og Sundhedsministeriet skal anmode om at modtage eventuelle bemærkninger til udkastet **senest mandag d. 6. marts 2023 kl. 12.**

Bemærkninger bedes sendt til sum@sum.dk og til cfma@sum.dk.

Camilla Friborg Madsen
Fuldmægtig, Kontor for Forebyggelse og Strålebestyttelse

M 21 67 75 18
@ cfma@sum.dk

INDENRIGS- OG SUNDHEDSMINISTERIET

Indenrigs- og Sundhedsministeriet
Tlf. 7226 9000

Læs ministeriets datapolitik **her**

www.sum.dk

GEJSER
E-CIGARETSPECIALISTEN

Galten, d. 1. marts 2023

Til Indenrigs- og Sundhedsministeriet

Høringssvar vedr.: Udkast til forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer (Implementering af dele af delegeret direktiv vedrørende opvarmede tobaksvarer samt andre præciseringer og tekniske justeringer)

Først og fremmest ønsker GEjSER at takke for muligheden for at kommentere på fremsendte lovforslag.

Det glæder os, at Indenrigs- og Sundhedsministeriets har et ønske om at tydeliggøre hvilke krav der skal stilles til alderskontrol, henholdsvis på fysiske salgssteder og ved salg online i forbindelse med salg af elektroniske cigaretter og tilbehør. Vi mener dog, at der bør foretages ensrettede og mere konkrete ændringer, som tydeliggør hvilke specifikke krav der stilles i forbindelse med aldersverificering, og særligt for online-salgssteder.

I GEjSER bakker vi op om De Samvirkende Købmænds forslag om elektronisk aldersverificering via. betalingskort[1], og vi er overbeviste om, at denne løsning især vil kunne forhindre salg af nikotinprodukter til børn og unge via. online-salgssteder. Derfor har vi naturligvis et håb om, at Indenrigs- og Sundhedsministeriet vil have løsningen med i overvejelserne, så ensretning for samtlige online-salgskanaler opnås. Vi mener der er behov for konkrete løsninger og yderligere præcisering på området, og her er elektronisk aldersverificering via. betalingskort et godt bud.

Vi anerkender, at der kan opstå tvivl i forbindelse med kontant-betalinger i forbindelse med salg på fysiske salgssteder, og derfor er det også glædeligt, at præciseringen vedr. krav om anmodning om fremvisning af gyldig billedlegitimation, hvis en ekspedient er i tvivl om en kundes alder, fremgår i lovforslaget.

Vi håber at Indenrigs- og Sundhedsministeriet vil tage GEjSER's forslag og betragtninger med i viderebehandlingen af lovforslaget, og vi takker endnu engang for muligheden for at få lov til at dele dem med jer.

Med venlig hilsen

Jeanett Andersen
Kommunikationsansvarlig

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[1] https://www.berlingske.dk/danmark/koebmaend-alderstjek-via-kreditkort-kan-hindre-salg-af-nikotinprodukter

HJERTE FORENINGEN

Indenrigs- og Sundhedsministeriet
Slotsholmsgade 10-12 – 1216 København K
E-mail: sum@sum.dk

Dato:
01. 03. 2023
Direkte tlf.: 51 28 22 43
E-mail:tcmoerch@hjerteforeningen.dk

Indenrigs- og Sundhedsministeriet har den 3. februar 2023 fremsendt udkast til:

Forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer (Implementering af dele af delegeret direktiv vedrørende opvarmede tobaksvarer samt andre præciseringer og tekniske justeringer)

Hjerteforeningen takker for muligheden for at kommentere forslaget om tilbagetrækning af undtagelser vedr. forbud mod smagsstoffer for opvarmet tobak samt andre præciseringer herunder lovhjemmel til aldersgrænser ved onlinesalg af tobak og alkohol.

Smagsstoffer til opvarmet tobak

Hos Hjerteforeningen er vi positivt indstillede over for, at der ikke må tilsættes smagsstoffer til opvarmet tobak. Tobak udgør den største enkeltstående risikofaktor for udviklingen af hjertesygdomme. Vidensråd for Forebyggelse konkluderer i en rapport fra 2022 om nikotinbrug blandt børn og unge, at der er stærk evidens for nikotins skadelige virkning på hjerte og kar, samt at der er større risiko for død ved eksisterende hjertesygdom/blodprop ved brug af nikotinholdige produkter. I litteraturen finder Vidensråd for Forebyggelse at en sammenhæng mellem tidlig udsættelse for nikotin og senere hjerte-kar-sygdom er sandsynlig. Det konkrete niveau for den øgede risiko for udvikling af hjerte-kar-sygdom kan ikke angives. Udviklingen af nye tobaks- og nikotinprodukter går hurtigt, og derfor er det nødvendigt at lovgivningen bliver tilpasset den udvikling, vi ser på markedet.

Ifølge WHO er der ikke evidens for, at opvarmet tobak er mindre skadeligt end andre former for tobak. Derfor er anbefalingerne, i henhold til WHO's rammekonvention om tobakskontrol, som Danmark og EU har ratificeret, at opvarmet tobak reguleres på samme måder som cigaretter.

Vi mener, at forbuddet mod smagsstoffer skal udvides, så det dækker alle typer af tobaksprodukter. Dertil er det også vigtigt, at smagsstofferne bliver forbudt som ingredienser, og ikke som "kendetegnende aromaer", så der ikke opstår usikkerhed om, hvor meget smag der må indgå i produktet.

Hjerteforeningen støtter, at opvarmet tobak fremover omfattes af samme forbud mod smagsstoffer, som gør sig gældende for cigaretter, og det er særligt vigtigt, da smagsstofferne gør produkterne mere tiltrækkende for børn og unge.

Onlinesalg af tobak og lignende produkter skal ikke være lovligt

Ved online salg af tobak, urtebaserede rygeprodukter, tobakssurogater og e-cigaretter, vil der med lovforslaget blive indført lovhjemmel til at stille krav om alderskontrol. Det er vi positivt indstillede overfor, men det er ikke tilstrækkeligt. Det er alt for nemt for forhandlere at indføre et skema, hvor forbrugeren siger ja til, at vedkommende er over 18. Som det fremgår af lovforslaget, bliver der først stillet krav til forhandlerne om at sikre et system, der effektivt verificerer køberens alder, når det kan sikres, "at den rette tilgængelige løsning til et effektivt alderskontrolsystem kan implementeres hos forhandlerne".

Vi mener, at det ikke skal være tilladt at sælge tobak og lignende produkter online, da vi den vej igennem kan mindske tilgængeligheden og markedsføring af de skadelige produkter for børn og unge.

Effektiv alderskontrol ved onlinesalg af alkohol

Det er en god udvikling, at der med lovforslaget bliver rettet op på den manglende lovhjemmel ift. aldersgrænser for onlinesalg af alkohol. Men da der heller ikke her stilles krav om, at kontrolsystemet for alder skal være effektivt, godkender lovgivningen på en måde den nuværende fremgangsmåde, hvor forbrugeren kan afkrydse, om vedkommende er fyldt hhv. 16 eller 18 år. Det nuværende alderskontrolsystem er derfor ikke tilstrækkeligt, da det stadig muliggør onlinesalg af alkohol til børn og unge.

Hjerteforeningen mener desuden, at der bør indføres en aldersgrænse på 18 år for køb af alle typer af alkohol. Det er også i overensstemmelse med Sundhedsstyrelsens anbefalinger, hvori børn og unge under 18 år frarådes at drikke alkohol.

Med venlig hilsen

Anne Kaltoft
Adm. direktør

24. februar 2023

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www.cancer.dk

UNDER PROTEKTION AF
HENDES MAJESTÆT DRONNINGEN

Indenrigs- og Sundhedsministeriet
sum@sum.dk og cfma@sum.dk

Høringssvar vedr. implementering af direktiv vedr. opvarmede tobaksvarer samt andre præciseringer, herunder alderskrav ved online salg af tobak og alkohol

Kræftens Bekæmpelse takker for muligheden for at kommentere på forslaget om tilbagetrækning af undtagelser vedr. forbud mod smagsstoffer for opvarmet tobak samt andre præciseringer herunder lovhjemmel til aldersgrænser ved online salg af tobak og alkohol.

Det er positivt, at der ikke må tilsættes smag til opvarmet tobak
Tobak er kræftfremkaldende og årsag til lungekræft og mindst 15 andre kræftformer. Der kommer hele tiden nye tobaks-og nikotinprodukter på markedet, og derfor er det vigtigt, at lovgivningen løbende tilpasses markedsudviklingen. Opvarmet tobak er et nyt produkt, og ifølge WHO er der ikke evidens for, at det er mindre skadeligt end andre former for tobak. WHO anbefaler, at opvarmet tobak reguleres på samme måde som cigaretter og anden tobak i henhold til WHO´s rammekonvention om tobakskontrol, som Danmark og EU har ratificeret.

I Kræftens Bekæmpelse bakker vi op om, at opvarmet tobak ifølge forslaget fremover omfattes af samme forbud mod smagsstoffer som cigaretter. Mentol og andre aromaer gør produkterne mere tiltrækkende for især børn og unge.

I den kommende revision af EU´s tobaksvaredirektiv mener vi, at forbuddet mod smagsstoffer fremover bør udvides til at gælde for alle typer af tobaksprodukter. Det er også vigtigt, at smagsstofferne ikke kun forbydes som "kendetegnende aromaer", men som ingredienser, så der ikke er usikkerhed om, hvor meget smag, der må tilsættes et produkt.

Online salg af tobak og lignende produkter bør ikke være tilladt.
Med lovforslaget indføres lovhjemmel til at stille krav om alderskontrol ved online salg af tobak, urtebaserede rygeprodukter, tobakssurrogater og e-cigaretter. Vi finder det som udgangspunkt positivt, at man nu retter op den manglende lovhjemmel. Men det er langt fra tilstrækkeligt, at forhandlerne blot kan nøjes med at lade forbrugerne krydse af, om de er 18 år, og at der først stilles krav om et reelt effektivt alderskontrolsystem, når " den rette tilgængelige løsning til et effektivt alderskontrolsystem kan implementeres hos forhandlerne."

I Kræftens Bekæmpelse mener vi, at online salg af tobak og lignende produkter slet ikke skal være tilladt jf. WHO´s anbefalinger. Det vil gøre tobak mindre tilgængeligt for især børn og unge og begrænse markedsføring af produkterne.

Online salg af alkohol kræver effektiv alderskontrol
Vi finder det positivt, at man også på alkoholområdet retter op på den manglende lovhjemmel i forhold til aldersgrænserne for alkohol ved online salg. Men eftersom der heller ikke her stilles krav om, at alderskontrolsystemet skal være effektivt, blåstempler lovgivningen de facto den nuværende praksis, som ikke forhindrer salg af alkohol til børn og unge.

Det er ikke tilstrækkeligt, at forbrugerne blot kan krydse af, at de er fyldt 16 eller 18 år. I dag er salg af alkohol til børn og unge udbredt, og hele 15 pct. af de 15-17-årige har købt alkohol online, viste en undersøgelse i 2021. Derfor mener vi ikke, at man bør tillade online salg af alkohol, før forhandlerne har et effektivt alderskontrolsystem.

Kræftens Bekæmpelse mener desuden, at der bør indføres en ensartet aldersgrænse på 18 år for køb af alle typer af alkohol. Det er også i tråd med Sundhedsstyrelsens udmeldinger, hvori børn og unge under 18 år frarådes at drikke alkohol.

Med venlig hilsen

Mette Lolk Hanak
Forebyggelseschef

Lungeforeningen

Indenrigs- og Sundhedsministeriet
Holbergsgade 6
1057 København K

Høringssvar vedr. implementering af direktiv vedr. opvarmede tobaksvarer samt andre præciseringer, herunder alderskrav ved online salg af tobak og alkohol

Lungeforeningen takker for muligheden for at kommentere på lovforslaget.

Opvarmet tobak skal reguleres på linje med cigaretter og anden tobak
Vi er i Lungeforeningen positive over for, at der lægges op til, at opvarmet tobak omfattes af samme forbud mod smagsstoffer som cigaretter. Mentol og andre aromaer gør produkterne mere tiltrækkende for særligt børn og unge og bør derfor forbydes. Vi mener også, at smagsstofferne fremover bør udvides til at gælde for alle typer af tobaksprodukter.

Tobak er hvert år årsag til mere end 13.600 dødsfald i Danmark, og for flere lungesygdomme er rygning årsagen til hovedparten af tilfældene, herunder lungesygdommen KOL, hvor ca. 9 ud af 10 tilfælde skyldes rygning. Der kommer hele tiden nye tobaks- og nikotinprodukter på markedet, og derfor er det vigtigt, at lovgivningen hele tiden tilpasses. WHO anbefaler, at opvarmet tobak reguleres på samme måde som cigaretter og anden tobak og derfor er det godt, at loven tilpasses i overensstemmelse hermed.

Onlinesalg bør helt forbydes
Med lovforslaget indføres lovhjemmel til at stille krav om alderskontrol ved onlinesalg af tobak, urtebaserede rygeprodukter, tobakssurrogater og e-cigaretter.

Vi finder det positivt, at der indføres lovhjemmel, men vi kan godt frygte om det er nok, da forhandlerne blot kan vælge at lade forbrugere krydse af, at de er over 18 år. Langt mere oplagt ville det være at forbyde onlinesalg af tobak og lignende produkter, som WHO anbefaler. Det vil gøre tobak mindre tilgængeligt for især børn og unge.

Vi bidrager gerne yderligere
Skulle vores høringssvar medføre spørgsmål eller ønske om yderligere drøftelse, står vi naturligvis til rådighed.

Med venlig hilsen

Anne Brandt
Direktør i Lungeforeningen

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Høringssvar

LÆGEFORENINGEN

HØRING: FORSLAG TIL LOV OM ÆNDRING AF LOV OM TOBAKSVARER M.V., LOV OM ELEKTRONISKE CIGARETTER M.V., LOV OM FORBUD MOD SALG AF TOBAK OG ALKOHOL TIL PERSONER UNDER 18 ÅR OG LOV OM RØGFRI MILJØER

3.marts 2023
Sagsnr: 2023-1608
Aktnr: 4989310

Lægeforeningen bakker op om at opvarmede tobaksvarer omfattes af forbud mod smagsstoffer og krav til alderskontrol for online salg af tobak og alkohol.

Lægeforeningen takker for muligheden for at kommentere på forslaget om tilbagetrækning af undtagelser vedr. forbud mod smagsstoffer for opvarmede tobaksvarer samt andre præciseringer, herunder lovhjemmel til aldersgrænse ved online salg af tobak og alkohol.

Positivt at opvarmet tobak omfattes af forbud mod smagsstoffer
Rygning er den enkeltfaktor, som forårsager mest sygdom og kræver flest liv. Hvert år er der 13.600 rygerelaterede dødsfald. Det er derfor vigtigt at sikre at færre børn og unge begynder at ryge.

De senere år er markedet for nye tobaks- og nikotinprodukter vokset eksplosivt. Det omfatter bl.a. opvarmet tobak. Lægeforeningen har derfor længe efterlyst politisk handling over for det voksende marked af nye tobaks- og nikotinprodukter såsom opvarmet tobak, e-cigaretter, nikotinprodukter, der ikke bruges som led i et rygestop. Mange af produkterne appellerer til børn og unge, hvis hjerner er særligt sårbare over for nikotin, og som risikerer at blive livsvarigt afhængige af nogle sundhedsskadelige produkter.

Lægeforeningen bakker derfor op om, at opvarmet tobak fremover omfattes af samme forbud mod smagsstoffer som cigaretter. Tobaksprodukter, uanset type, bør ikke være tilsat mentol eller andre smagsstoffer, der gør tobaksprodukterne mere tiltrækkende for børn og unge.

Positivt med krav til alderskontrol ved online salg af tobak
Lægeforeningen finder det samtidig positivt, at det bliver muligt at stille krav til alderskontrol ved online salg af tobak, urtebaserede rygeprodukter, tobakssurrogater og e-cigaretter. Børn og unges adgang til tobak skal mindskes på alle platforme, så færre begynder at ryge.

Positivt med krav til alderskontrol ved online salg af alkohol
Det er veldokumenteret, at en effektiv håndhævelse af alderskontrollen nedsætter børn og unges alkoholforbrug. Det er derfor positivt, at det også på alkoholområdet bliver muligt at stille krav til alderskontrol ved online salg.

Desuden mener Lægeforeningen, at der hurtigst muligt skal indføres en aldersgrænse på 18 år for køb af alle typer alkohol, hvilket også er i tråd med

Formanden
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Sundhedsstyrelsens anbefalinger. Unge er i særlig risiko for skadevirkninger af alkohol, og en høj aldersgrænse er et af de mest effektive redskaber til at reducere unges alkoholforbrug.

Med venlig hilsen

Camilla Noelle Rathcke
Formand for Lægeforeningen

Nikotinbranchen

Indenrigs- og Sundhedsministeriet
Sagsnr.: 2213653
Dok. nr.: 2523532
sum@sum.dk
cfma@sum.dk

marts 2023

Udkast til forslag til lov om ændring af lov om tobaksvarer (Implementering af dele af delegeret direktiv vedrørende opvarmede tobaksvarer m.m.)

Nikotinbranchen kvitterer for muligheden for at kommentere "Udkast til forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer (Implementering af dele af delegeret direktiv vedrørende opvarmede tobaksvarer samt andre præciseringer og tekniske justeringer)" – herefter benævnt "forslaget".

Nikotinbranchens medlemmer producerer ikke opvarmet tobak – herefter benævnt "THP" (tobacco heating products), men vi finder det aktuelt at kommentere på forslaget, da det overordnet vedrører regulering af røgfrie nikotinprodukter per se og i sammenligning med reguleringen for cigaretter/røgtobak.

Forslagets indhold

Dette delegerede direktiv rummer disse for Nikotinbranchen relevante elementer:

Der lægges op til, at sælgere af tobak og alkohol skal kunne kræve forevisning af billedlegitimation, hvis der er tvivl om købers alder. Denne del af forslaget er relevant for Nikotinbranchen, fordi salg af røgfrie nikotinprodukter til mindreårige er et problem.

Det vil fjerne den hidtil gældende undtagelse for THP i forhold til forbuddet om brug af "kendetegnende aromaer" i produkterne.

Kommenterede delelementer

ID-kontrol
Det er positivt, at man med forslaget sikrer en tilstrækkelig tydelig hjemmel for krav om alderskontrolsystem ved salg fra hjemmesider, men det er efter Nikotinbranchens opfattelse bekymrende at der endnu ikke er taget konkrete skridt for indførsel af krav om ID-kontrol både ved salg fra fysiske butikker og hjemmesider.

Dels ved vi, at alt for mange børn og unge har adgang til at købe nikotinprodukter i butikker trods eksisterende aldersgrænse og skiltning herom, dels bliver det i for stort omfang alene den

individuelle ekspedients ansvar at bede om og kontrollere ID, og det er ikke en rimelig opgave at pålægge personalet i detailhandlen.

En del nikotinprodukter forhandles via nettet, og vi finder det derfor oplagt, at man har symmetriske regler online såvel som i fysiske butikker. Det kunne f.eks. ske ved, at man ved online køb ikke alene skal klikke af, at man er over 18 år, men også mødes af tofaktorgodkendelse i form af krav om aldersverifikation med digital ID.

I fysiske butikker kunne løsningen bestå af automatisk data i elektronisk betalingssammenhæng.

Nikotinbranchen foreslår, at man fra myndighedernes side etablerer en samlet plan for at nedbringe salget af nikotinprodukter til personer under 18 år såvel i fysiske butikker som på internettet. Nikotinbranchen bidrager gerne med input og viden om det illegale salg fra medlemmernes complianceindsats.

Kendetegnende aromaer og manglende differentiering mellem produktkategorier
Nikotinbranchen betragter forslaget om forbud mod kendetegnende aromaer i THP som problematisk i sin principielle tilgang, da det sidestiller THP og cigaretter for så vidt angår kravet om, at kendetegnende aromaer ikke må findes i såvel THP som cigaretter/røgtobak.

Det er grundlæggende problematisk at regulere cigaretter og traditionelle tobaksvarer på samme vis som røgfrie nikotinprodukter – herunder THP – idet produkterne er væsensforskellige for så vidt angår skadesvirkninger for den enkelte, gener og potentielle sundhedsrisici for omgivelserne og samfundsomkostningerne i forlængelse af brugen af produkterne.

Kendetegnende aromaer og smag er en for mange brugere afgørende forskel og incitament til at skifte fra cigaretter til røgfrie produkter som THP, e-cigaretter og nikotinposer.

Skadesreduktion

Rygning koster hvert år 13.600 danske liv. Antallet af rygere ligger stabilt med en let opadgående tendens trods års indsats i form af oplysning, forbud og stigende afgifter.

Med nikotinposers entré på det danske marked i 2019 faldt antallet af rygere, og det understøtter opfattelsen af røgfrie nikotinprodukters rolle som en realistisk vej væk fra cigaretterne for mange rygere.

I Sverige har man kendt til snus som røgfrit nikotinprodukt i årtier, og her er man tæt på at nå den fælles europæiske målsætning om maks. 5 pct. daglige rygere. Det er på tide i Danmark at tage ved lære af Sverige, men også lande som Storbritannien og New Zealand, hvor man regulerer røgtobak hårdt, men går på to ben og anerkender røgfrie nikotinprodukters skadesreducerende potentiale.

Reguleringen af cigaretter/røgtobak og røgfrie nikotinprodukter bør afspejle væsensforskellene mellem kategorierne og give incitament for rygere til at skifte fra røg til røgfri. Det kan bl.a. ske ved at fastholde, at forbuddet mod kendetegnende aromaer gælder for cigaretter men ikke for røgfrie alternativer.

Indstilling

Nikotinbranchen forstår Danmarks forpligtelse til at implementere EU-lovgivningen i dansk ret, men vil alligevel opfordre til, at Danmark i EU-regi fordrer en evidensbaseret tilgang til skadesreduktion og de folkesundhedsmæssige gevinster, der er at hente i anerkendelsen heraf.

Nikotinbranchen står til rådighed for drøftelser med myndigheder og lovgivere.

Med venlig hilsen

Inger Schroll-Fleischer, direktør
Nikotinbranchen

Nikotinbranchen
+45 22650919 ● isf@nikotinbranchen.dk ● www.nikotinbranchen.dk

Udkast til forslag til lov om ændring af lov om tobaksvarer (Implementering af dele af delegeret direktiv vedrørende opvarmede tobaksvarer m.m.)

Vi skal hermed afgive høringssvar om ændring af lov om tobaksvarer med henblik på at implementere det delegerede direktiv vedrørende opvarmede tobaksvarer.

Vi synes det et en dårlig ide at forbyde smage i opvarmede tobaksvarer. Smagene er vigtige elementer i at få rygere til at kvitte cigaretter og vælge et mindre skadeligt produkt, såsom opvarmet tobak. Dermed mener vi, at det nye forbud vil få skadelige konsekvenser for folkesundheden, idet færre rygere vil have incitament til at forlade cigaretterne til fordel for røgfri tobaksprodukter.

Vi konstaterer dog, at implementeringen af det delegerede direktiv holder sig inden for de rammerne af vedtagelserne på EU-niveau. Og vi lægger vægt på, at man sondrer mellem tobaksvarer, der er røgprodukter (med forbrænding) og tobaksvarer, der er røgfri (uden forbrænding).

Med venlig hilsen

NBL
NÆRBUTIKKERNES LANDSFORENING

Jesper Lundberg
formand

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Website: www.nbl-landsforening.dk
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Anna Dunø Madsen

Fra: Niels Jørgen Langkilde - Patientforeningen <njl@patientforeningen.dk>
Sendt: 15. februar 2023 20:48
Til: Camilla Friborg Madsen; DEP Sundhedsministeriet
Emne: SV: Høring: Udkast til forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer

Til Indenrigs- og Sundhedsministeriet
Att: Camilla Friborg Madsen

Alene sendt på sum@sum.dk og cfma@sum.dk

Patientforeningen takker for muligheden for at kommentere på lovforslaget om ændring af Lov om tobaksvarer mmm.

Patientforeningen har ingen kommentarer til lovforslaget, og Patientforeningen kan anbefale, at det fremsættelse.

De bedste hilsener

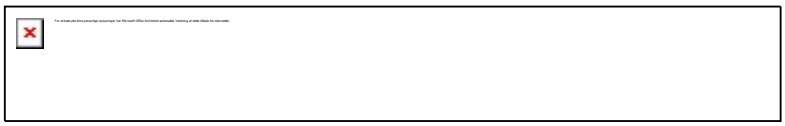
Mag. art. Niels Jørgen Langkilde, fhv. MF,

Formand,

Patientforeningen,

Rishøjvej 2, 2. sal th

5672 Broby



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CVR.nr.: 30011538

For et frit læge- og sygehusvalg

Fra: Camilla Friborg Madsen <CFMA@SUM.DK>
Sendt: 3. februar 2023 09:26

Til: Advoksamfundet <samfund@advokatsamfundet.dk>; info@alkohologsamfund.dk; ac@ac.dk; ka@ka.dk; Arbejdstilsynet <arbejdstilsynet@at.dk>; Astma-Allergi Forbundet <info@astma-allergi.dk>; Bsinfo@baggersorensen.com; formand@becig.dk; bkd@blaakors.dk; post@branchedanmark.dk; info_dk@bat.com; Danske Læskedrik Fabrikanter (info) <info@bryggeriforeningen.dk>; Børnerådet <brd@brd.dk>; bv@bornsvilkar.dk; kontakt@cfh.ku.dk; forbrugerservice@forbruger.coop.dk; kontakt@dagrofa.dk; Danmarks Apotekerforening <apotekerforeningen@apotekerforeningen.dk>; farmaceutiske-selskab@pharmadanmark.dk; info@lunge.dk; Danmarks Restauranter og Cafeer <drc@thehost.dk>; da@da.dk; formand@dadafo.dk; Dansk Erhverv (info) <info@danskerhverv.dk>; Emballageindustrien <hoering@di.dk>; dls.dlsoffice@gmail.com; Helen.gerdrup.nielsen@regionh.dk; dsam@dsam.dk; psykiatri@regionh.dk; administration@dsff.dk; info@patientsikkerhed.dk; support@bilka.dk; dsr@dsr.dk; Dansk Transport og Logistik (DTL) <dtl@dtl.eu>; fysio@fysio.dk; kontakt@dgsnet.dk; dh@handicap.dk; info@danskepatienter.dk; Danske Regioner <regioner@regioner.dk>; info@danske-seniorer.dk; dse@skoleelever.dk; info@dansktp.dk; info@danske-aeldreraad.dk; Post@dataetiskraad.dk; Datatilsynet <dt@datatilsynet.dk>; dsk@dsk.dk; dommerforeningen@gmail.com; Det Etiske Råd kontakt <kontakt@etiskraad.dk>; Diabetesforeningen <info@diabetes.dk>; sales@efuma.com; kontakt@eeo.dk; foa@foa.dk; fh@fho.dk; hero@fho.dk; bla@fho.dk; EUI@fho.dk; Faglig Fælles Forbund 3F <3f@3f.dk>; ff@farmakonom.dk; fa@fanet.dk; 1 - KFST Forbrugerombudsmanden (KFST) <FO@Forbrugerombudsmanden.dk>; 1 - KFST Forbrugerombudsmanden (KFST) <FO@Forbrugerombudsmanden.dk>; Forbrugerrådet <hoeringer@fbr.dk>; hf@fadl.dk; fas@dadl.dk; kontakt@fdih.dk; info@fpmdk.dk; hs@fpmdk.dk; fp@fogp.dk; mal@fogp.dk; himr@himr.fo; Gigtforeningen <info@gigtforeningen.dk>; Hjerteforeningen <post@hjerteforeningen.dk>; horesta@horesta.dk; info@oliver-twist.dk; oliver-twist@oliver-twist.dk; info@igldk.dk; info.dk@jti.com; sek@jordemoderforeningen.dk; national@kfum-kfuk.dk; kk@kirkenskorshaer.dk; kfs@sundkom.dk; Kommunernes Landsforening <KL@KL.DK>; Kræftens Bekæmpelse <info@cancer.dk>; los@los.dk; lh@handelselever.dk; lo@lo.dk; Lægeforeningen <dadl@dadl.dk>; Brancheforeningen for Lægemiddelvirksomheder i Danmark (LIF) <info@lif.dk>; medico@medicoindustrien.dk; ungdom@danskmetal.dk; cach@danskmetal.dk; moedrehjaelpen@moedrehjaelpen.dk; govsec@nanoq.gl; NVK Kontakt <kontakt@nvk.dk>; DKetik Institutionspostkasse <DKetik@DKetik.dk>; isf@nikotinbranchen.dk; Nærbutikkernes Landsforening <info@nbl-landsforening.dk>; nnf@nnf.dk; Offentligt Ansattea Organisationer <oao@oao.dk>; info@pfldk.dk; Medlem - Patientforeningen <medlem@patientforeningen.dk>; Niels Jørgen Langkilde - Patientforeningen <njl@patientforeningen.dk>; info@patientforeningen-danmark.dk; pd@pharmadanmark.dk; info@pharmakon.dk; christoffer.arzrouni@pmi.com; Pmaps@pmi.com; plo@dadl.dk; pto@pto.dk; info@rigsrevisionen.dk; kontakt@roegfrifremtid.dk; Rådet for Socialt Udsatte <post@udsatte.dk>; post@skole-foraeldre.dk; Jeanett@SMOKE-IT.dk; Jens@SMOKE-IT.dk; support@gejser.dk; info@smokesolution.com; benny.husted@ssp-samraadet.dk; post@sundbynetvaerket.dk; info@sundheddanmark.nu; shk@sundhedskartellet.dk; silkeborg@swedishmatch.com; info@sygeforsikring.dk; info@tandlaegeforeningen.dk; jh@tobaksindustrien.dk; info@tobaksproducenterne.dk; info@vinordic.org; aeldresagen@aeldresagen.dk; yl@dadl.dk
Emne: Høring: Udkast til forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer

Til alle høringsparter

Se venligst vedhæftede høring over udkast til forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer (Implementering af dele af delegeret direktiv vedrørende opvarmede tobaksvarer samt andre præciseringer og tekniske justeringer)

Indenrigs- og Sundhedsministeriet skal anmode om at modtage eventuelle bemærkninger til udkastet **senest mandag d. 6. marts 2023 kl. 12.**

Bemærkninger bedes sendt til sum@sum.dk og til cfma@sum.dk.

Camilla Friborg Madsen
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Indenrigs- og Sundhedsministeriet

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København den 21. februar 2023

Udkast til forslag til lov om ændring af lov om tobaksvarer (Implementering af dele af delegeret direktiv vedrørende opvarmede tobaksvarer m.m.)

Vi takker for muligheden for at kommentere "Udkast til forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer (Implementering af dele af delegeret direktiv vedrørende opvarmede tobaksvarer samt andre præciseringer og tekniske justeringer)" – herefter omtalt som "Forslaget".

Med dette forslag gennemfører Danmark Kommissionens delegerede direktiv (EU) 2022/2100 af 29. juni 2022 om ændring af Europa-Parlamentets og Rådets direktiv 2014/40/EU (TPD) med hensyn til tilbagetrækning af visse undtagelser for opvarmede tobaksvarer (det delegerede direktiv).

Lovens indhold

Gennemførelsen af dette delegerede direktiv vil fjerne den undtagelse, som har været gældende for opvarmede tobaksvarer, i forhold til forbuddet mod at bruge kendetegnede aromaer.

Desuden vil det påbyde brugen af kombinerede sundhedsadvarsler og den generelle informationsmeddelelse i henhold til art. 9 og 10 i TPD for de opvarmede tobaksprodukter, der er blevet klassificeret som tobaksvarer til rygning i overensstemmelse med art. 2(5) TPD.

Vigtige juridiske hensyn

Gennemførelse af det delegerede direktiv skal ske i overensstemmelse med art. 114 TEUF og må ikke resultere i en forvridning af det indre marked eller en krænkelse af Acquis Communautaire generelt. Dette indebærer, at den nationale lovgivning klart skal skelne mellem mærkningsreglerne for opvarmede tobaksprodukter, der ikke involverer en forbrændingsproces, og dem, der er klassificeret som tobak til

rygning. Førstnævnte vil skulle anvende sundhedsadvarsler i henhold til art. 12 TPD, mens sidstnævnte skal overholde art. 9 og 10 i TPD i denne henseende.

Vi noterer os Danmarks hensigt om at gennemføre det delegerede direktiv inden for de retlige rammer for Acquis Communautaire og derfor alene kræve kombinerede sundhedsadvarsler for de opvarmede tobaksprodukter, der er klassificeret som rygetobak og involverer en forbrændingsproces:

"Endvidere medfører det delegerede direktiv en ændring af artikel 11, stk. 1, i tobaksvaredirektivet, således opvarmede tobaksvarer, for så vidt de er røgtobak, fremover ikke kan undtages fra bestemmelserne om påføring af den informationsmeddelelse, der er fastsat i artikel 9, stk. 2, i tobaksvaredirektivet og de kombinerede sundhedsadvarsler, der er fastsat i artikel 10 i tobaksvaredirektivet (Forslagets side 7)

Forslaget fremmer desværre ikke folkesundheden

Med hensyn til tilsætningsstoffer vil gennemførelsen af det delegerede direktiv føre til en sidestilling af reguleringen for opvarmede tobaksprodukter med brændbare tobaksprodukter såsom cigaretter og finskårne tobaksprodukter.

Selvom denne regulering er resultatet af et krav i TPD efter en "væsentlig ændring i forholdene" i betydningen af art. 2 (28) TPD, er det imidlertid en udvikling, der ikke vil gavne folkesundheden.

Sundhedsministeriet giver udtryk for, at det delegerede direktivs gennemførelse vil gøre *"opvarmede tobaksvarer mindre attraktive og, for så vidt de opvarmede tobaksvarer er røgtobak, at gøre forbrugere mere opmærksomme på de sundhedsrisici, der er forbundet med at anvende opvarmede tobaksvarer. Det vurderes, at direktivet således vil bidrage til at begrænse forbruget af opvarmede tobaksvarer, herunder at børn og unge indleder et forbrug." (Forslagets side 7)*

I den forbindelse vil vi gerne påpege, at der ifølge Eurobarometer-data stort set ingen, der påbegynder et nikotinforbrug via opvarmede tobaksvarer – ligesom kun få påbegynder nikotinforbrug via e-cigaretter[1].

Nationale undersøgelser i EU bekræfter dette resultat[2].

Vi henviser i øvrigt til præsentationen af "Vidensråd for Forebyggelse" i Folketingets sundhedsudvalg den 10. juni 2021, hvor det blev oplyst, at kun 0,7 pct. af unge rygere er blevet introduceret til nikotin gennem opvarmet tobak[3].

For opvarmede tobaksvarer understøttes denne vurdering af den seneste rapport fra Europa-Kommissionen om en væsentlig ændring i forholdene for opvarmede tobaksvarer. Rapporten: *"did not identify 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 heated tobacco products"*[4].

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[1] Eurobarometer Special Report 506, p. 97.

[2] I Tyskland er andelen af unge, der bruger opvarmede tobaksprodukter 0,3 %, ifølge tal fra det tyske føderale center for sundhedsuddannelse (BZgA), se:
https://www.bzga.de/fileadmin/user_upload/PDF/pressemitteilungen/daten_und_fakten/Info-Blatt_01._Juli_2020.pdf
For e-cigaretter er denne andel 0,5 % i Tyskland, ifølge de seneste tal fra DEBRA-undersøgelsen fra Kölns Universitet, se: https://www.debra-study.info/wp-content/uploads/2022/02/Factsheet-07-v5.pdf

[3] (https://www.ft.dk/samling/20201/almdel/SUU/bilag/475/2415957.pdf

[4] COM(2022) 279 final: Report from the Commission on the establishment of a substantial change of circumstances for heated tobacco products in line with Directive 2014/40/EU – se:

Dette viser, at alternativer til cigaretter for det meste anvendes af voksne rygere og ikke af mindreårige eller ikke-rygere. Desværre vil forbuddet mod kendetegnende aromaer i opvarmede tobaksvarer sandsynligvis gøre det mindre oplagt for voksne rygere at skifte til disse produkter, hvilket vi vil uddybe yderligere nedenfor.

Brug for tobaksskadereduktion og differentieret regulering

Den bedste måde at undgå skaderne ved rygning er, at man aldrig begynder, eller at eksisterende rygere holder op. Men virkeligheden er, at mange ikke opfører sig sådan.

Det er vores opfattelse, at de mennesker, som ellers ville fortsætte med at ryge, fortjener en pragmatisk tilgang og en fornuftig løsning, der flytter dem væk fra brugen af cigaretter, som er den mest skadelige måde at forbruge nikotin på ifølge videnskaben.

Europa-Kommissionen påpeger, at 700.000 europæere dør for tidligt af rygning årligt[5]. I Danmark er dette tal 13.600.

Den eneste måde at nedbringe dette tal er at gennemføre regulering, der fremskynder ophøret af rygning. Der er stærke uafhængige internationale beviser for skadesreduktion indenfor tobak. Derfor bør rygestop fremskyndes ved at gøre brug af de positive erfaringer med skadesreduktion.

Tilskyndelser til rygestop fremmes bedst ved hjælp af en differentieret regulering baseret på skadevirkningerne forårsaget af tobaks- og nikotinholdige produkter i forhold til deres toksicitet.

Her må det være tilsynsmyndighedernes primære mål at reducere cigaretternes tiltrækningskraft (ved at fremme ikke-initiering og tilskynde til ophør), idet cigaretterne er den mest skadelige måde at levere nikotin på.

Samtidig bør voksne rygere, som ellers ville fortsætte med at ryge , have mulighed for at vælge bedre, røgfri alternativer såsom opvarmede tobaksvarer.

Sådanne politikker bør indebære differentierede regler, både med hensyn til kommunikation og med hensyn til emballage, mærkning og ingredienser. Det vil sikre, at bedre alternativer skal være korrekt mærkede i overensstemmelse med deres egenskaber. Desuden skal de være kendte og accepterede i forhold til voksne rygere.

Smagenes rolle for tobaksskadereduktion

Forbuddet mod kendetegnende aromaer i opvarmede tobaksvarer indebærer desværre, at disse produkter nu reguleringsmæssigt de facto bliver ligestillet med de langt mere skadelige produkter såsom cigaretter og rulletobak.

Forskellige smagsvarianter spiller en væsentlig rolle for voksne rygere i forhold til at få dem til at skifte væk fra cigaretter. Et forbud mod kendetegnende aromaer reducerer dermed rygeres incitamenter til at skifte til skadesreducerende produkter. Det vil tilmed kunne få brugere, som anvender mindre skadelige opvarmede tobaksprodukter til at skifte tilbage til cigaretter.

[5] Background document on the Call For Evidence to Evaluate the Tobacco Control Framework Ref. Ares(2022)3824008, - se: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13481-Evaluation-of-the-legislative-framework-for-tobacco-control_en

Det er kendt fra rygestop, at andre smage end tobak i røgfri alternativer til cigaretter støtter rygere i at holde op[6].

Empiriske data tyder på, at et forbud mod smag i røgfri alternativer endda kan have den utilsigtede konsekvens at øge rygefrekvensen ved at modvirke skift: En undersøgelse udført i San Francisco viste, at rygestop for voksne og skift til røgfri produkter var mere effektivt for de voksne, der brugte e-cigaretter uden tobakssmag. Undersøgelsen konkluderer:

"Critically, this study's findings suggest that efforts to ban flavored e-cigarettes could increase smoking: nontobacco flavors were no more strongly associated with youth smoking initiation than tobacco flavors but were more strongly associated with adult cessation. Given limited sample sizes, further work is needed"[7]

Anbefaling

Selvom PMI forstår, at Danmark er nødt til at gennemføre EU-lovgivningen, anbefaler vi kraftigt, at Danmark arbejder konstruktivt for at modernisere EU's tobakskontrolramme og forholde sig positivt til den evidensbaserede tilgang til tobaksskadereduktion. På den måde kunne Danmark demonstrere sit lederskab globalt med henblik på at bidrage til at skabe en røgfri verden. En sådan tilgang vil også fremme transformationen af tobaksindustrien, som har en afgørende rolle at spille i at fremskynde denne overgang til en røgfri fremtid. Det skyldes industriens evne til at udvikle bedre røgfri alternativer, der kan erstatte rygning.

Vi står til rådighed for en åben og gennemsigtig dialog om fremtidens tobaksregulering i Danmark.

Med venlig hilsen

Christopher Arzrouni

Philip Morris ApS

Copenhagen Towers

Ørestads Boulevard 108, 3. sal

2300 København S

[6] Romijnders et al (2019): E-Liquid Flavor Preferences and Individual Factors Related to Vaping: A Survey among Dutch Never-Users, Smokers, Dual Users, and Exclusive Vapers, in Int J Environ Res Public Health, 4661

[7] Friedman 2020 Associations of Flavored e-Cigarette Uptake With Subsequent Smoking Initiation and Cessation

From: Marie Vibe Jørgensen <marie.vibe.joergensen@regionh.dk>
Sent: 01-03-2023 12:41:46 (UTC +01)
To: Camilla Friborg Madsen <CFMA@SUM.DK>; DEP Sundhedsministeriet <sum@sum.dk>
Subject: SV: Høring: Udkast til forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer - intern frist den 24. februar 2023

Til Indenrigs- og Sundhedsministeriet

Hermed høringssvar fra Region Hovedstaden. Til orientering har vi modtaget høringen via Region Hovedstadens Psykiatri, som høringen blev sendt direkte til fra jer, og vi har på den baggrund koordineret et samlet høringssvar fra Region Hovedstaden.

Det er et komplekst og omfattende materiale, og erfaringerne fra tidligere er, at tobaksindustrien hurtigt vil tilpasse deres produkter til de muligheder, som loven giver. Det kræver derfor meget stor faglig viden at forholde sig til lovforslaget, hvorfor vi har forhørt os hos Charlotta Pisinger, som er professor i tobaksforebyggelse ved Center for Klinisk Forskning for Forebyggelse, Frederiksberg Hospital. Charlotta har sammen med Dansk Selskab for Folkesundhed gennemgået lovforslaget og udarbejdet vedlagte svar. Region Hovedstaden støtter op om høringssvaret fra Dansk Selskab for Folkesundhed.

Med venlig hilsen

Marie Jørgensen
Juridisk konsulent

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Emne: Høring: Udkast til forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer

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Indenrigs- og Sundhedsministeriet skal anmode om at modtage eventuelle bemærkninger til udkastet **senest mandag d. 6. marts 2023 kl. 12.**

Bemærkninger bedes sendt til sum@sum.dk og til cfma@sum.dk.

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Indenrigs- og Sundhedsministeriet
Att. Camilla Friborg Madsen

Høring: Udkast til forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer (Implementering af dele af delegeret direktiv vedrørende opvarmede tobaksvarer samt andre præciseringer og tekniske justeringer)

SSP-Samrådet

Benny Husted
Formand
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Skanderborg den 06.03.2023

SSP-Samrådet takker for muligheden for at kommentere *"Udkast til forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer (Implementering af dele af delegeret direktiv vedrørende opvarmede tobaksvarer samt andre præciseringer og tekniske justeringer)".*

SSP-Samrådet har følgende bemærkninger til det fremsatte lovforslag:

- Det er positivt, at opvarmede tobaksvarer omfattes af de eksisterende regler om forbud mod markedsføring af produkter med kendetegnende aroma eller aromastoffer.
- Det er ligeledes positivt, at lovgivningen omkring alderskontrol præciseres, særligt i forhold til online-salg. Det er dog en svaghed, at man ikke pt. har et tilgængeligt system, der entydigt kan identificere køber som værende over 18 år.
  SSP-Samrådet har ikke tiltro til at et alderskontrolsystem, der er baseret på en tilkendegivelse af alder, vil have den ønskede effekt. Der bør fortsat arbejdes på et alderskontrolsystem der er baseret på en teknisk hindring af muligheden for at gennemføre et online køb, såfremt man ikke kan dokumentere, at man er over 18 år.

På vegne af SSP-Samrådet

Benny Husted
Formand

Pernille Ødegaard Skovsted
Næstformand

6. marts 2023

Høringssvar fra Sund By Netværket

Vedr. høring til Udkast til forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer.

Sund By Netværket har gennem sin temagruppe med fokus på forebyggelse af brugen af tobak, damp, snus og nikotinprodukter, kigget på lovforslaget. Temagruppens medlemmer, der repræsenterer 52 danske kommuner, har følgende bemærkninger:

Generel kommentar om strukturelle rammer

Tobak- og nikotinprodukter finder desværre vej til vores børn og unge, i mange af de miljøer de befinder sig i, i hverdagen – fx i skolen og foreningslivet. I kommunerne i Danmark arbejdes der hver dag med forebyggelse af udfordringerne, men både Sygdomsbyrderapporten (Sundhedsstyrelsen, 2023) og rapporten Nikotinbrug blandt børn og unge (Vidensråd for Forebyggelse, 2022), viser behovet for at vi har et yderligere fokus her. Og her har de strukturelle greb en afgørende betydning. Med afsæt i viden om de kendte skadevirkninger, og udfordringen med særligt børn og unges stigende forbrug af nikotinprodukter, kunne vi således ønske, at det blev langt sværere for børn og unge at begynde på produkterne, hvorfor vi som fagligt netværk savner et langt større fokus på:

- Håndhævelse af allerede eksisterende lovgivning – 18års grænsen skal overholdes (nikotinens skadelige virkning for unge helt op til 25-30års alderen kunne endda tale for at grænsen skulle hæves yderligere)
  Der skal afsættes tilstrækkelige økonomiske ressourcer og kapacitet til at fastholde eller ligefrem øge kontrollen på tobaks- og nikotinområdet, så nærværende lovgivning som minimum håndhæves. Det er desuden ikke lykkes med håndhævelse af nikotinfrie miljøer i fx skoletiden (på trods af – men muligvis pga. ikke tydelig – lovgivning på området)

- Der skal være flere røgfrie- og nikotinfrie miljøer hvor børn og unge færdes
  Gerne i foreningslivet, i biografen, på diskoteker og i byens rum. Alt sammen med det formål at indskrænke de rum og miljøer i hverdagslivet, hvor børn og unge disponeres for produkterne

- Priserne på tobak- og nikotinprodukter skal sættes op
  *Endelig vil vi gerne appellere til **højere prissætning på tobaks- og nikotinprodukter** i tillæg til det strukturelle greb med røg- og nikotinfrie miljøer. En flerstrenget lovgivning, som skruer på alle knapperne til gavn for folkesundheden nu og her, såvel som for kommende generationer.*

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c/o KL-huset
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2300 København S
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www.sund-by-net.dk

Ønske om ulovliggørelse

Det ultimative ønske **til gavn for folkesundheden** er et egentlig forbud mod tobaks- og nikotinprodukter. Den netop offentliggjorte sygdomsbyrde rapport bakker i høj grad op om dette – i tillæg til nyeste viden om nikotinprodukternes skadelig virkning på børn og unge.

Strukturelle greb som lovgivning og forbud understøtter forebyggelsesarbejdet i kommunerne hvorfor vi hilser forslag om lovændringer på dette område velkommen, med følgende bemærkninger til lovteksten:

Skildring mellem medicinsk nikotin og nydelses nikotin

Det er et stærkt ønske om at **produkter der går under betegnelsen 'nikotinprodukter'** *(bortset fra nikotinprodukter der er godkendt til medicinsk forbrug, herunder rygestopmedicin eller behandlingsnikotin)* **gennem lovteksten underlægges samme lovgivning, som tobaksprodukter** (i teksten omtalt som tobaksvarer, tobakssurrogater eller urtebaserede rygeprodukter). Det betyder, at vi meget gerne ser produkterne omtalt, så det er tydeligt, at disse produkter er omfattet af loven som et 'nydelses nikotinprodukt'.

Med den nuværende betegnelse 'røgfri tobak', der bruges i nærværende lovtekst åbnes en mulighed for producenterne om at omgå lovgivningen så blandt andet produkter som nikotinposer, der ikke indeholder tobak, kommer på markedet uden yderligere kontrol.

Der ønskes desuden en **grænseværdi for nikotinindholdet** i 'nydelsesnikotinprodukterne, hvor vi ligeledes gerne ser en **tydelig produktinformation på produkterne**.

Det undrer os, at vi som sundhedsfaglige (kommunalt) ansatte, er underlagt delegeret ansvar fra Lægemiddelstyrelsen når vi vejleder borgere, der skal købe hjælpemidler til rygestop – når borgere kan gå i enhver kiosk eller supermarked og købe et nikotinprodukt (hvor vi ikke altid kender indholdet af nikotin), som pga. manglende lovgivning på området, findes i utrolig mange afskygninger.

På vegne af Sund By Netværket

Lene Bruun og Ditte Kirkegaard Madsen
Formandskabet for Sund By Netværkets bestyrelse

Sund By Netværket

Swedish Match

Indenrigs- og Sundhedsministeriet
Sagsnr.: 2213653
Dok. nr.: 2523532
sum@sum.dk
cfma@sum.dk

København, den 6. marts, 2023

Høringssvar fra Swedish Match Danmark vedr. Udkast til forslag til lov om ændring af lov om tobaksvarer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer (Implementering af dele af delegeret direktiv vedrørende opvarmede tobaksvarer samt andre præciseringer og tekniske justeringer)

Swedish Match Danmark takker for muligheden for at indgive kommentarer vedr. udkast til forslag til lov om ændring af lov om tobaksvarer m.v. Swedish Match Danmark producerer og sælger nikotinposer og spundne røgfri tobakspastiller fra vores fabrik i Silkeborg og vores datterselskab House of Oliver Twist i Odense.

Vi fremsender hermed vores bemærkninger til alderskontrol i forbindelse med online salg af nikotinprodukter.

De nuværende regler er, efter vores mening, desværre ikke tilstrækkelige, da der ses et udbredt salg af røgfri nikotinprodukter til personer under 18 år. Jf. en nylig publiceret rapport fra Sundhedsstyrelsen om brug af røgfri nikotinprodukter blandt unge mellem 15-29 år fremgår det, at de 15-17-årige er den aldersgruppe, der i størst omfang køber de røgfri nikotinprodukter online fra danske og udenlandske hjemmesider.

Udkastet til lovforslaget adresserer problemet med manglende lovhjemmel, mens det fortsat er lige uvist, hvordan alderskontrolsystemerne ved onlinesalg skal udformes for at være fyldestgørende og sikre, at kundens aldersoplysning bliver effektivt verificeret.

På hjemmesider, hvor der sælges røgfri nikotinprodukter, er det allerede standard med en aktiv tilkendegivelse af, at den besøgende er fyldt 18 år. I praksis handler det derfor kun om indførsel af en funktion, der effektivt verificerer oplysningen om alder for at efterleve bestemmelsen og dens formål.

Swedish Match foreslår derfor, at man, ved registrering som sælger af tobaksvarer ved fjernsalg, skal præsentere et alderskontrolsystem der, udover aktiv tilkendegivelse af alder, samtidig indeholder en funktion, som verificerer den angivne alder ved at indhente supplerende oplysninger om kunden.

Det kunne være et krav om at registre sig som kunde med indgivelse af oplysninger, der understøtter den angivne alder, for at få adgang til at handle fra den pågældende website. Det

vil ikke eliminere risikoen for falsk profil, men det vil gøre det mere omstændigt og besværligt for den mindreårige at handle online.

Det udbredte onlinesalg til mindreårige betyder, efter vores bedste overbevisning, at man ikke bør afvente udviklingen af et officielt alderskontrolsystem, der helt eliminerer risikoen for mindreåriges adgang til køb af nikotinprodukter fra hjemmesider. Vi mener, at der snarest, efter nærværende lovforslags vedtagelse, bør indføres krav til sælgere af tobaksvarer ved fjernsalg om at anvende alderskontrolsystemer med en dobbelt foranstaltning, der indeholder både en aktiv tilkendegivelse af alder og en konkret funktion for verifikation af den oplyste alder.

Med venlig hilsen

Rune Siglev
Public Affairs Director

Indenrigs- og Sundhedsministeriet
Kontor for Forebyggelse og Strålebeskyttelse
Att.: Fuldmægtig Camilla Friborg Madsen
Slotsholmsgade 10-12
1216 København K

Tandlægeforeningen
Amaliegade 17
1256 København K

GAN
Høring 003_2023
Dato: 6. marts 2023

Vedr.: Høring om forslag til lov om ændring af lov om tobaks-varer m.v., lov om elektroniske cigaretter m.v., lov om forbud mod salg af tobak og alkohol til personer under 18 år og lov om røgfri miljøer

Tandlægeforeningen takker for det modtagne udkast til høring og har følgende generelle bemærkninger til de regulatoriske ændringer, der lægges op til i det fremsendte materiale:

Tandlægeforeningen noterer sig, at opvarmede tobaksvarer som følge af det delegerede direktiv (Europa-Parlamentets og Rådets direktiv 2014/40/EU) omfattes af artikel 7, stk. 1 og 7, i tobaksvaredirektivet.

Implementering af direktivet i dansk ret betyder, at forbuddet mod markedsføring af tobaksvarer med en kendetegnende aroma eller med aromastoffer i deres bestanddele såsom filtre, papir, emballage, kapsler eller enhver teknisk funktion, der gør det muligt at ændre de pågældende tobaksvarers duft eller smag eller deres røgudviklingsintensitet, som allerede findes for cigaretter og rulletobak, udvides til også at omfatte opvarmede tobaksvarer. Dette finder Tandlægeforeningen af sundhedsfaglige grunde hensigtsmæssigt.

Tobak er langt den væsentligste årsag til mundhulekræft og andre alvorlige sygdomme i mundhulen som fx parodontitis – en sygdom, der har sammenhæng med diabetes og hjertekarsygdomme, ligesom parodontitis kædes sammen med psoriasis, leddegigt, osteoporose, Alzheimers sygdom og Parkinsons sygdom.

Forskning viser, at opvarmede tobaksvarer skader cellerne i munden på samme niveau, som var man udsat for tobaksrygning, og vi ved også, at det øger risikoen for parodontitis og tandtab. På den baggrund vurderer Tandlægeforeningen, at en udvidelse af forbuddet mod markedsføring af opvarmede tobaksvarer kan gavne folkesundheden.

I forlængelse af ovenfornævnte påskønner Tandlægeforeningen det planlagte lovforslag, der indeholder en præcisering af kravene til alderskontrol og Sundhedsstyrelsens skilte. Tandlægeforeningen noterer sig videre, at der i lovforslaget lægges op til at styrke alderskontrollen online, når den rette løsning er tilgængelig. I den sammenhæng mener Tandlægeforeningen, at det er afgørende, at der ligeledes tages initiativ til et effektivt alderskontrolsystem på fysiske salgssteder, fx ved brug af aldersverificering på betalingskort.

Tandlægeforeningen har ikke yderligere bemærkninger.

Med venlig hilsen

Susanne Kleist, tandlæge mTF
Formand

Isabel Brandt Jensen
Direktør

Sund mund - Sund krop #SundmundSundkrop

From: Jens Hennild <jh@tobaksindustrien.dk>
Sent: 28-02-2023 09:18:46 (UTC +01)
To: DEP Sundhedsministeriet <sum@sum.dk>
Cc: Camilla Friborg Madsen <CFMA@SUM.DK>
Subject: Vdr. j.nr.2213653 : Høring over udkast til ændring af lov om tobaksvarer mv.

Indenrigs- og Sundhedsministeriet
Att:sum@sum.dk og cfma@sum.dk.

Tak for anledningen til at kommentere på ovennævnte lovudkast.

Vi noterer os, at udkastet bl.a. implementere de nye EU regler for opvarmet tobak der ifølge udkastet, skal træde i kraft d. 23. oktober 2023. Vi tillader os her at gå ud fra, at Sundhedsstyrelsen i god tid inden da, har udstedt en bekendtgørelse, som nærmere beskriver hvilken type advarsel de pågældende produkter skal være påført.

Vi skal samtidig udtrykke støtte til udkastets intention om at styrke håndhævelsen af det eksisterende forbud mod salg af tobaks- og nikotinprodukter til mindreårige .

Udkastet giver i øvrigt ikke anledning til bemærkninger.

Med venlig hilsen

Tobaksindustrien

Jens Hennild
Direktør, Cand.jur.

Tobaksindustrien

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