TOX/2018/20

COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT (COT)

Potential toxicological risks from electronic nicotine (and non-nicotine) delivery systems (e-cigarettes). Follow up to paper 2: Additional information on reports describing the presence of silicon/silicates in the aerosol of E(N)NDS

Background

1. As part of a review of the possible human health effects of electronic nicotine delivery systems and electronic non-nicotine delivery systems (E(N)NDS – 'e-cigarettes'), a review of published studies on potential exposure to metals from E(N)NDS use was discussed at the March 2018 COT meeting (TOX/2018/15).

2. This review described a study by Williams and colleagues that had reported that silicon was the most abundant element (> 50%) of the elemental particulate matter in aerosols produced from some disposable E(N)NDS products (Williams et al. 2017). The authors concluded that the silicon was derived from fragments of fibreglass in the sheath and wick of the E(N)NDS device that had broken off and passed into the aerosol, and they commented that the presence of silicates in E(N)NDS aerosols may be of health concern and should be evaluated further.

3. While discussing TOX/2018/15 at the March 2018 COT meeting, Members requested more information on the presence and form of silica in E(N)NDS aerosols. Further information that could be identified is described in the following paragraphs.

Studies by Williams et al.

4. Williams and colleagues reported a series of three studies in which they investigated the structural components of E(N)NDS devices by disassembling the devices and assessing how the components observed may correlate with the presence of metal particles in aerosols produced from these devices. Two of these studies discussed the presence of silicon/silicates.

5. In a first report, Williams et al. (2013) dissected 22 cartomizers from a US 'leading manufacturer' of E(N)NDS, purchased over a two-year period (brand not stated, but all were the same non-nicotine product type). Cartomizers consisted of a cylindrical sheath or mouthpiece with a white silica gasket, a wick, which appeared to be fibreglass, thick and thin filaments, an air tube, four solder joints, inner dense

fibres, and outer fibres of Poly-fil[1]. Components from one dissected E(N)NDS device are shown in Figure 1.

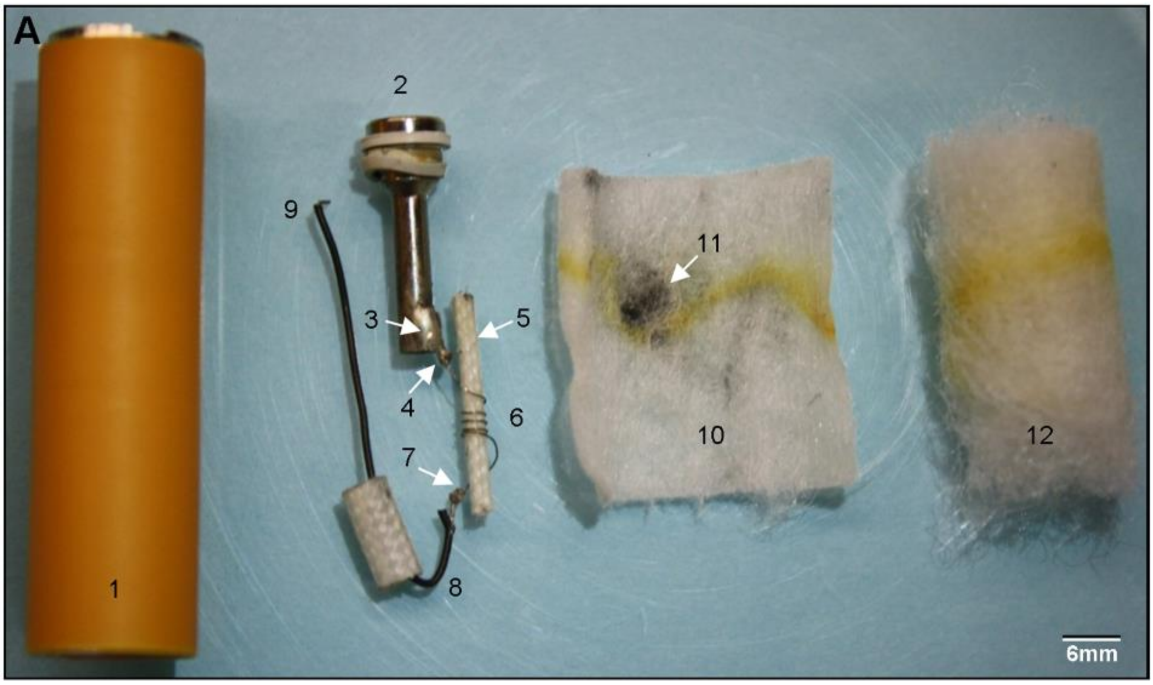

Figure 1. Components of a disassembled cartomizer-type E(N)NDS. Component 5 is the wick. Reproduction of Figure 1 from Williams et al. (2013) PLoS ONE, 8(3): e57987.

6. Aerosol produced from these cartomizers was analysed in comparison with room air. Aerosol was captured in a 200 mL beaker containing either a pin stub for scanning electron microscopy (SEM) or a formvar-coated copper grid for transmission electron microscopy (TEM). A total of 15 (SEM) or 60 (TEM) 4.3-s puffs were collected using a fully charged battery and fresh cartomizer, and the grids or stubs were evaluated by FEI XL30 SEM using backscatter and/or secondary electron imaging modes or FEI CM300 TEM, respectively. Elemental analysis was carried out by energy dispersive x-ray spectroscopy (EDS). The number of particles per puff was counted using a TSI 3772 Condensation Particle Counter. Particle size was analysed using a TSI 3080 Scanning Mobility Particle Sizer and Condensation Particle Counter, using aerosol collected in a glass jar. Controls were processed in the same manner as E(N)NDS aerosol, but using room air.

7. Room air contained relatively few, small particles, while one E(N)NDS puff contained numerous particles distributed in two broad peaks (Figure 2 A,B). TEM/EDS analysis indicated nanoparticles (< 100 nm) of tin, chromium, and nickel. SEM/EDS microanalysis in the range 1–20 µm (Figure 2 C,D) indicated numerous bright particles (tin, silver, nickel, aluminium, iron, cerium, lanthanum, bismuth, zinc). In addition, numerous round particles of various sizes that were less bright in the

[1] Polyester fibrefill

backscatter electron mode were observed, which contained mainly silicon with lesser amounts of magnesium, aluminium, and calcium. These silicate beads were considered to originate from the fibreglass wick, which was reported to have small, round, smooth-surfaced particles on its surface of a similar size, appearance, and elemental composition as the silicate beads in the aerosol (Figure 2 I).

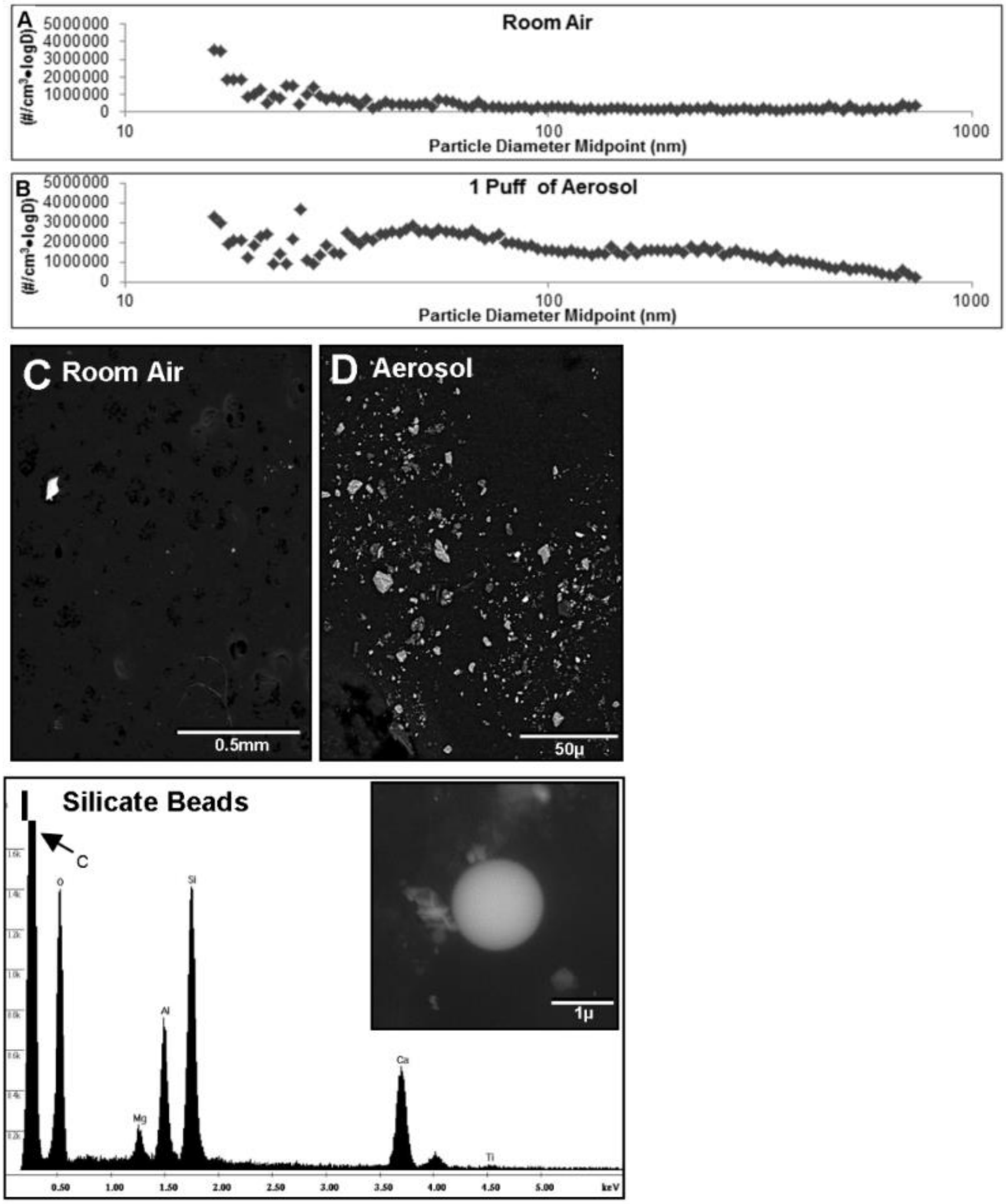

Figure 2. Particulate material in E(N)NDS aerosol. Size distribution of particles in room air (A) and aerosol (B). SEM micrographs of particles seen in room air (C) and aerosol (D), viewed in backscatter mode. (I) EDS spectrum and SEM micrograph of silicate beads in E(N)NDS aerosol. Adapted from Figure 4 of Williams et al. (2013) PLoS ONE, 8(3): e57987

8. Abundance of the various particles was measured by inductively coupled plasma optical emission spectroscopy (ICP-OES). The most abundant elements were silicon (2.24 µg/10 puffs), calcium (1.03 µg/10 puffs), aluminium (0.394 µg/10 puffs), and magnesium (0.066 µg/10 puffs), which corresponded to the elements observed in the silicate beads and fibreglass wick. The authors suggested that the round, smooth-surfaced silicate beads could pass through the outer fibres more readily than irregular-shaped particles (e.g. tin), which would become trapped. They commented that the fibreglass wicks may be breaking down and releasing beads due to heating and the high airflow rates required to operate the particular brand of E(N)NDS device studied.

9. In a follow-up study, Williams et al. (2017) evaluated eleven E(N)NDS devices (six disposable 'e-cigarettes' (ECs) and five disposable 'e-hookahs' (EHs)), containing E(N)NDS liquids of various flavours, with or without nicotine. Inspection of the disassembled devices showed similar structures in all E(N)NDS devices. Elemental analysis of dissected components by SEM/EDS showed that, in all brands, the sheaths were composed of silicon, oxygen, calcium, aluminium, and magnesium, with silicon being the dominant element. The sheaths of two brands (Luxury Lites and Smooth) also contained sodium, and the sheath of NJOY King contained only silicon, oxygen, and calcium (Figure 3 A-F, M). Wicks were predominantly silicon and oxygen, mostly with the same composition as the sheath, except for Luxury Lites, in which the sheath lacked magnesium (Figure 3 G-L, N).

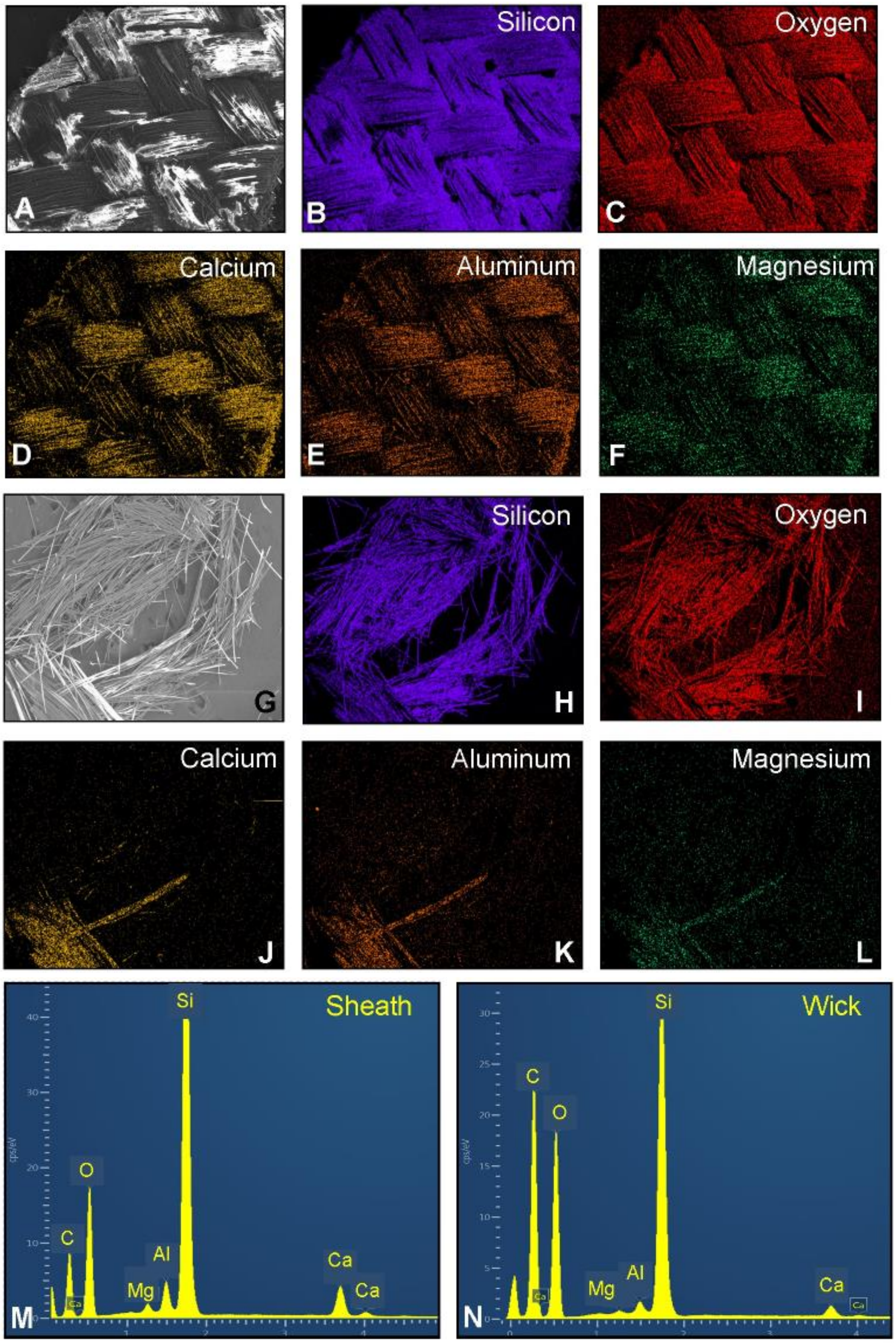

Figure 3. SEM/EDS analysis of disposable wicks and sheaths of E(N)NDS ('e-cigarettes and e-hookahs'). Examples are shown for the brand 'BluCig'. Sheath (A) and composition (B-F); Wick (G) and composition (H-L); Spectra of the sheath (M) and wick (N). Reproduction of Figure 8 from Williams et al. (2017) PLoS ONE 12(4): e0175430

10. Levels of 36 elements were measured by ICP-OES analysis in the aerosols produced from the different E(N)NDS devices (subtracted against room air), and comparison was made with a reference conventional cigarette (CC; Marlboro Red). A total of 31 elements were identified across the spectrum of the 11 E(N)NDS aerosols at levels ≥ 0.001 µg/10 puffs, with 17 elements detected in one or more brands at levels > 0.01 µg/10 puffs. Silicon was the most abundant element identified in the aerosols of all E(N)NDS brands (> 50% by total mass; range, 0.094–6.835 µg/10 puffs). Silicon was also the most common element identified in CC smoke (0.752-4.171 µg/10 puffs; 56%-98% by total mass, in aerosol obtained by ISO protocol[2]).

11. The authors concluded that the most likely source of the aerosolised silicon was the sheath and wick, which were described as being ‘made of finely woven silicate glass threads with minor sodium, potassium, calcium, and magnesium (fibreglass) that can easily break when handled.’ It was proposed that fragments of the sheath/wick broke off during manufacturing or were released during heating/cooling cycles, which was supported by a blackened and damaged appearance near the filament. The authors concluded that further work is needed to determine the potential health effects of the silicon and silicate fibreglass inhaled in E(N)NDS aerosols.

Other studies summarised in the TOX/2018/15 report on metals in E(N)NDS

12. Of the papers summarised in TOX/2018/15, only one other study had reported the presence of silicon in E(N)NDS aerosols (Lee et al. 2017). In this study, energy dispersive X-ray fluorescence spectrometry was used to analyse the presence of 48 elements in aerosol produced from V2 cigalike cartomizer devices (1.8% nicotine; tobacco, menthol flavours). The report stated that of the 48 elements analysed, trace amounts of barium, chlorine, indium, and silicon were detected in some samples, with the other elements being below the limit of detection. However, results/data relating to these findings were not presented in the report.

Search for additional literature

13. A literature search was performed to determine whether further literature reporting the presence of silicon/silicates in E(N)NDS aerosols could be identified. The databases, Scopus and PubMed were searched on 05/04/18 with the terms (‘e-cig*’ OR ‘electronic cigarette*’ OR ‘electronic nicotine delivery system’) AND ‘silic*’, limit English language.

14. Fourteen publications were identified (14 on Scopus, 4 on PubMed), of which 12 were excluded (6 mentioned silica in relation to aerosol collection/analysis techniques; 4 were review articles; 1 was an article on burns from explosion of

2 International Organization for Standardization protocol (ISO, 2.2-second puff, puff volume of 35 ml, every minute)

E(N)NDS devices; 1 article discussed modelling *in silico*). The remaining two publications were those of Williams et al. (2013) and Williams et al. (2017) that are described above.

15. In conclusion, no additional literature on the presence of silicon/silicates in E(N)NDS aerosol was identified.

Questions for the Committee

16. Members are asked to consider this paper and in particular:

i. Is anything further required with respect to the potential presence and form of silicon/silicates in E(N)NDS aerosols?

ii. Does the Committee wish to make any comment on silicon/silicates in E(N)NDS aerosols in the statement on the topic in due course?

References

Lee, M. S., R. F. LeBouf, Y. S. Son, P. Koutrakis & D. C. Christiani (2017) Nicotine, aerosol particles, carbonyls and volatile organic compounds in tobacco- and menthol-flavored e-cigarettes. *Environmental Health: A Global Access Science Source,* 16.

Williams, M., K. Bozhilov, S. Ghai & P. Talbot (2017) Elements including metals in the atomizer and aerosol of disposable electronic cigarettes and electronic hookahs. *PLoS ONE,* 12.

Williams, M., A. Villarreal, K. Bozhilov, S. Lin & P. Talbot (2013) Metal and Silicate Particles Including Nanoparticles Are Present in Electronic Cigarette Cartomizer Fluid and Aerosol. *PLoS ONE,* 8.

Abbreviations

CC	Conventional cigarette
EC	Electronic cigarette
EH	Electronic hookah
E(N)NDS	Electronic nicotine or electronic non-nicotine delivery system
EDS	Energy dispersive X-ray spectroscopy
ICP-OES	Inductively coupled plasma optical emission spectroscopy
SEM	Scanning electron microscopy
TEM	Transmission electron microscopy

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