Written evidence submitted by BSMW Ltd (ECG0052)

1. BSMW Ltd is one of the UK’s leading e-liquid manufacturers based in an advanced production centre in the North West. The company was founded by Ben Wilson in 2010 and grew at an immense rate through innovation and dedication to the industry. BSMW Ltd was acquired in 2016 by STADA (Germany) who also own UK pharmaceutical company, Thornton & Ross, one of the largest OTC pharmaceutical manufacturer behind leading brands such as Covonia, Zoflora and Headrin.

Being the only Vaping business owned by a recognised pharmaceutical company, the business has reached high service and production levels that are above and beyond other competitors, resulting in winning deals to supply to large retail giants and wholesalers. As a company, we produce in excess of 2 million fully tested and regulated e-liquids each month and have invested in approximately £3,000,000 into a production facility that meets the regulatory framework that was put in place. BSMW Ltd. have recognised the market trends and accommodated the needs of the customer through convenience, retail and premium products. In May 2017, the business achieved ISO 9001:2016 certification through exceptional production facilities and a high-level quality management system. In addition to this, BSMW Ltd have gained Authorised Partner Status with Warrington Borough Council to gain a full understanding of how trading standards work and to assist with the ever-changing industry.

As a business, BSMW Ltd. are dedicated to maintaining a high level of professionalism and being at the forefront of addressing issues posed within the industry.

2. BSMW Ltd. recognise that there are many other issues surrounding the vaping market sector (including the health, regulatory and financial implications) but as a company we feel the regulations surrounding certain products, and what is being allowed on the market is currently the largest threat facing the industry. This may eventually in turn destroy an industry that can support and assist with the governments vision of ‘a smoke-free generation’. Short Fill Products that are making there way onto the Vaping Market are a complete by pass of the regulations that were originally put into place to safe-guard public health. Due to the nature of the products that aren’t regulated within the Tobacco Products Directive these can therefore pose health problems for the public through ignorance of the ingredients that they contain.

BSMW Ltd. will be challenging both the Department of Health and the MHRA to contest these products, that do not go through the same rigorous application as nicotine containing products to ensure that they are safe to market and safe to consume.

3. According to research conducted by ECig Intelligence, Shortfill products now account for more than half the available range of vapour products in some markets. Recent figures have shown that 50% of the German, French and Greek market have moved to short fill, with the demand becoming increasingly higher (Tim Phillips, ECig Intelligence 2017). The main reason behind this, is a more convenient bottle size and a cost saving of around 40%. Currently the UK market stands at 20% and is increasing every month. It will affect 10ml sales across the board.
This is expected to continue to grow in both existing markets and through introduction to new markets. This is of great concern due to the unregulated nature of the nicotine-free flavoured e-liquids that are less rigorously tested, and therefore less safe than those that contain nicotine. This new form of e-liquid product usually consists of a larger 60ml capacity bottle that is short-filled to around 50ml of non-nicotine flavour e-liquid, containing 50ml PG/VG and flavouring. The 10ml remaining space is for the customer to add their own nicotine shot to take it to a 3mg strength e-liquid. The nicotine shot is 18mg, usually consisting of Nicotine, PG and VG. This provides a workaround for the EU TPD that requires all nicotine containing products to be in a maximum 10ml bottle and registered through the EUCEG gateway.

Registrations consist of the nicotine containing products to be Toxicological Emission Tested from a reputable UKAS accredited laboratory. During the vaporisation process, the e-liquid is heated to temperatures that are often above 300°C. These temperatures are sufficiently high enough to induce physical changes of the e-liquid and may cause chemical reactions between the constituents. The ingredients of e-liquid (propylene glycol, vegetable glycol and flavouring) have been shown to thermally decompose at high temperatures, which may generate low molecular weight carbonyl compounds with established toxic properties such as formaldehyde, acetaldehyde and acrolein.

The test method used to determine the carbonyls compounds is designed to generate the amount of aerosol under controlled sampling conditions from the specified e-liquid, this is then captured in a solution that is required to enable chromatographic separation and detection. The resulting liquid samples are stabilised and then analysed using a liquid chromatography and tandem mass spectrometric detection (HPLC-MS/MS). The tests consist of analysing the liquid for chemical components such as Formaldehyde, Acetaldehyde, Acrolein, Crotonaldehyde, Diacetyl and Acetyl Prionyl.

Due to the nature of the Shortfill product, these are not required to go through the emission testing as they do not fall under TPD and therefore are not needed to be tested at this level. This is leading to products being placed on the market that have been confirmed to contain the chemical
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compounds that if found in nicotine containing e liquid, would not be allowed within the vaping industry.

4. Some companies are testing their nicotine-free e liquid to the same TPD minimum standards that are required for their e liquids with nicotine. It is currently unknown how many companies are carrying out these tests and how widespread the non-compliance of short fill products is. Not all countries are accepting nicotine-free e liquid notifications, for example Germany is accepting this type of product under an ‘other’ category whilst the MHRA within the UK is not accepting them at all. It has since been confirmed from the MHRA’s Beryl Keeley that manufacturers and producers can submit 0mg products through the EU CEG portal, if they feel they wanted to add credibility to their product although they will still be charged a notification fee for this, a massive deterrent for manufacturers.

To further confirm the chemical compounds that are found within the short fill products, various manufacturers have submitted short fill products for emission and GCMS testing. Below shows the results from five samples of short fill products that are currently available on the shelf for the consumer to purchase.

Method Summary: 5g of the sampled e-liquid was weighed into a 10ml headspace vial and sealed. The sample was heated to 55°C and agitated for 10 minutes. 0.5ml of air was sampled from the headspace of the vial and injected onto the GC-MS column. Compounds were detected using Mass Spectrometry with Selected Ion Monitoring (SIM) for ions specific to 2,3-Butanedione (Diacetyl) and 2,3-Pentanedione (Acetyl propionyl). The compounds were quantified by comparing the ion responses to e-liquid standards of a known concentration.

Results:

<table>
<thead>
<tr>
<th>Sample</th>
<th>2,3-Butanedione (Diacetyl) concentration (µg g⁻¹, ppm)</th>
<th>2,3-Pentanedione (Acetyl propionyl) concentration (µg g⁻¹, ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>N.D*</td>
<td>924</td>
</tr>
<tr>
<td>Sample 2</td>
<td>N.D*</td>
<td>337</td>
</tr>
<tr>
<td>Sample 3</td>
<td>N.D*</td>
<td>913</td>
</tr>
<tr>
<td>Sample 4</td>
<td>N.D*</td>
<td>34</td>
</tr>
<tr>
<td>Sample 5</td>
<td>N.D*</td>
<td>1193</td>
</tr>
</tbody>
</table>
The results clearly show that out of the five samples that were analysed using the above method, all five of them contain 2,3-Pentanedione or Acetyl propionyl concentration.

In addition to this, we also conducted our own tests on 3 samples of short fill products. The results showed one of the samples contained Acetoin which is an irritant to skin, eyes, mucous membranes and lungs. It has also been found to metabolize in a similar way to diacetyl.

Acetyl propionyl is a substitute for diacetyl that has been proven to cause a variety of health problems. Although they are deemed safe for use in food, they have been associated with the development of respiratory dysfunction when inhaled. This flavouring has previously been used to give microwave popcorn its buttery taste, but has also been implicated in the case of eight popcorn factory workers who developed a lung condition called sever bronchiolitis obliterans after breathing it in. A NIOSH (National Institute for Occupational Safety and Health) stated that they documented a relationship between cumulative exposure to diacetyl vapour over time and having abnormal lung function as measured by a test of lung function called spirometry. In addition to this, subsequent studies have helped to clarify the dangers of diacetyl. Toxicology studies have shown that vapours from heated butter flavourings can caused damage to airways in animals (Hubbs et al, 2002). Studies in both rats and mice demonstrate that the cells lining the airways can be damaged by inhaling diacetyl vapours as a single agent exposure in both acute and sub chronic studies.

2,3 Pentanedione is a flavouring substitute for diacetyl as it is structurally extremely similar to diacetyl. A recent NIOSH publication documents that acute inhalation exposures to 2,3-Pentanedione causes airway epithelial damage that is similar to diacetyl in laboratory studies (Hubbs et al. 2012).

Furthermore, we have commissioned a report with Bibra to investigate the health-precautionary tolerable levels for six key carbonyl e-liquid analytes. The report details the tolerable exposure limits (µg/inhalation) for Acetaldehyde, Acetyl Propionyl, Acrolein, Crotonaldehyde, Diacetyl and Formaldehyde. The report has provided further evidence that the short fill products currently available within the market contained levels of certain carbonyls that exceed Bibra’s tolerable exposure limits.

5. It is clear short fill products that are becoming increasingly popular on the vaping market pose not only a threat to businesses but to the actual consumer.

Some countries have chosen to regulate non-nicotine containing e liquids in the same fashion that nicotine products are regulated. Countries such as France, Denmark, Netherlands, Belgium, Slovakia, Slovenia, Austria and Hungary all apply the same restrictions for e-liquids within nicotine equally to nicotine-free liquids. Unregulated products are being sold from American and Malaysia and are increasingly taking over the market. Again, these products will contain chemical compounds that although are deemed safe within food flavourings, are not safe to inhale.

Despite the evidence being clear on the implications of short fill products, caution is needed when approaching this topic, especially with the media and publishers. It needs to be made clear that it is not the size of the bottle that is the issue here as the 10ml maximum limit bottle is a regulation that makes no difference to the health impacts of the e liquid.

Short fill products are clearly posing a threat to the e-cigarette industry, with one speaker at the Next Generation Nicotine Delivery conference describing the products as a ‘time-bomb’. Regardless of Short fill products providing a cost saving alternative, due to not having to test non-nicotine e-
liquids, this is obviously leading to a variety of issues within the industry, the most prominent being the chemical compounds that are found in these products.

In the long term, the worse thing that can happen within this industry is the public reading headlines that describe vaping as unsafe or containing chemical compounds that may link to respiratory issues. Proposals surrounding this area pose significant flaws. Creating new regulations that relate to these types of products could lead to new policies being added to the TPD, thus restricting the industry more than it is already. Whilst some companies may dispute a regulation that surrounds non-nicotine products due to the cost implications, it is vital that something is done to control and regulate short fill e liquid to prevent reports of serious illness being described as a direct result of vaping.

This will eventually affect the industries reputation that has been slowly built through research from reputable sources i.e. Cancer Research, and which has the potential of becoming an immense health prize thus giving it a bad name through public perception.

http://journals.sagepub.com/doi/pdf/10.1177/0192623307312694
https://www.cdc.gov/niosh/topics/flavorings/exposure.html
https://www.cdc.gov/niosh/topics/flavorings/exposure.html
https://ecigintelligence.com/is-shake-and-vape-a-ticking-time-bomb-for-the-vaping-industry/

6. Supporting Companies:

Vape & Juice
Freddy & George
I Love Vapour
My Nu Age
Electric Tobacconist
SLAM Trading
Can You Get Me
eCloud

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