



Ministry of Health and Elderly

Vejle, 21.02.2020

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Consultative response to: Draft draft law amending the law on the ban on tobacco advertising, etc., the Tobacco Products Act, etc., the Electronic Cigarettes Act, etc. and various other laws (Implementation of the National Action Plan against children and young people's smoking¹)

Att. Health Minister Magnus Heunicke and the government's support parties on the national action plan against children and young people's smoking

DADAFO - The Danish Vapers Association's consultation response, is primarily focused on the proposed amendments and additions to "Act No. 426 of 18/05/2016 - Electronic Cigarette Act etc."

DADAFO would like to say thanks, for at least in connection with the consultation, we are allowed to contribute with our opinions. Perhaps it would have been better, fairer and timely if we had been consulted before the bill was written, so that both the minister and the politicians from the government's support parties had gained from our experience and knowledge before agreeing on the proposals for the tobacco trade plan.

DADAFO is generally positive that the government and parties in the Folketing (Parliament) are finally making a focused effort to limit smoking in Denmark, especially in view of the fact that there has been no decline in smoking prevalence in recent years, as has been the case in several of the our neighboring countries (England, Sweden, Norway and Iceland for example)

DADAFO is skeptical of how effective neutral packages and exhibition bans will actually be, especially in light of reports from countries where these measures have already been introduced. We see it primarily as a symbolic policy towards the tobacco companies. However, we have no objection to this if it is aimed solely at tobacco products. In fact, these measures will not adversely affect consumers, since cigarettes are a reasonably homogeneous product and therefore there is no basis for the appearance to have an impact on the consumer.

This is not the case with e-cigarette/vaping products.

¹ http://www.sum.dk/Aktuelt/Nyheder/Forebyggelse/2019/December/~/media/Filer%20-%20dokumenter/01-tobak/Aftaletekst.pdf





DADAFO sees it as a defect in the legal documentation that no risk profiles have been assessed for different products, and in fact all products are conflated - whether or not they contain tobacco. The consumer is entitled to real and factual information that some products are actually less harmful to health than others and that tobacco harm reduction can be the way forward for many consumers.

Most of the legislation that has been passed in the e-cigarette field has been created on the basis of a lack of factual knowledge, based on estimates and guesses. And unfortunately, this is also the case with the European Parliament and of the Councils directive (2014/40/EU - **TPD**) - in particular Title III, Chapter 20² - specifically dealing with e-cigarettes, and is no exception.

The framework of EU legislation was adopted on a far too flimsy basis, and was urged by the European Parliament in 2013/2014, as an addendum to the directive - which otherwise only dealt with specific tobacco products.

Evaluation of TPD is due to be carried out in 2020/2021 and is still unpublished. This evaluation should form the basis for a new revision of the TPD. Denmark is therefore premature and rushed in relation to changes in the TPD basis, as the results of the evaluation are not yet available.

As a minimum, all proposals for amendments to the "Electronic Cigarette Act, etc." should be taken out of the Bill / National Action Plan until the EU Commission has submitted their evaluation.

When once adopted at a supranational level, a legislation/frameworks for regulation that directly stops development and innovation, and stops an otherwise positive development in the decline in smoking prevalence, then almost all subsequent national legislation based on the supranational EU law, help to impose additional restrictions and regulations.

In its introductory recitals TPD states, (paragraphs 45, 53, 54) and in particular Article 20 (1). 10, Article 24 2 and 3 (see below) that the <u>directive actually introduces a high level of health protection</u> and that further prohibitions <u>must be</u> justified on the basis of a risk to general public health and that the prohibition does not discriminate:

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

EU Tobacco Product Directive, Article 24, pkt. 3

² https://ec.europa.eu/health/sites/health/files/tobacco/docs/dir_201440_da.pdf



Furthermore, clear guidelines from the EU / Commission have been laid down on how the precautionary principle should apply to <u>all legislation</u> at both EU and national level, including how further restrictions and regulation must be justified before it can be approved by the Commission.

From the summary of the "precautionary principle" as defined in "Communication from the Commission on the precautionary principle - COM (2000) 1 final":

Common guidelines

The precautionary principle shall be informed by three specific principles:

- the fullest possible scientific evaluation, the determination, as far as possible, of the degree of scientific uncertainty;
- a risk evaluation and an evaluation of the potential consequences of inaction;
- the participation of all interested parties in the study of precautionary measures, once the results of the scientific evaluation and/or the risk evaluation are available.

In addition, the general principles of risk management remain applicable when the precautionary principle is invoked. These are the following five principles:

- proportionality between the measures taken and the chosen level of protection;
- non-discrimination in application of the measures;
- consistency of the measures with similar measures already taken in similar situations or using similar approaches;
- examination of the benefits and costs of action or lack of action;
- review of the measures in the light of scientific developments.

Lack of risk assessment and impact assessment

As stated in the Commission guidelines, due diligence has not been carried out in connection with the proposed legislative changes and additions to especially the "Electronic Cigarette etc. Act".

In the proposed amendments law, the "precautionary principle" is not taken into account, and thus the bill is not made on the basis of risk assessments and impact assessments.

The proposed amendments law does not focus on proportionality between the individual potential health effects of products. By way of comparison, of course, one does not bestow the same punishment on a person who kills another human being – as a person who walks out into a pedestrian crossing when the light is red. As mentioned, there must be proportionality in legislation so that consumers are protected and human rights are respected.

DADAFO, as an association for consumers of e-cigarettes in Denmark, strongly points out that there is a wide difference between tobacco cigarettes and e-cigarettes/vapes. There are now no scientific experts who will continue to claim that tobacco cigarettes and e-cigarettes carry the same risk when used, but on the contrary, consensus has been created that e-cigarettes are significantly less harmful than tobacco smoking.

³ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM%3Al32042

⁴ https://eur-lex.europa.eu/legal-content/DA/TXT/PDF/?uri=CELEX:52000DC0001&from=DA



This fact must result in a distinction in legislation governing the regulation of products!

This is already the case in Danish legislation, as the "Electronic Cigarette etc. Act" deals exclusively with these products and the "Tobacco Products Act" exclusively deals with products containing tobacco. Also, note that e-vapor/e-cigarettes are not (and should never be) covered by the "Smoke-Free Environments Act". Both because it is not smoke, but especially because it is a work environment law, and therefore must be based on an objective assessment of emissions in relation to the limit values given for work environments.

DADAFO believes that <u>it is in violation of the EU directive to impose restrictions on e-cigarettes without the full health implications being elucidated</u>. On the Danish side, it must be possible to present and justify that these restrictions are imposed on the basis of <u>an acute deterioration in overall public health</u>.

The Danish Health Authority's (DHA - Sundhedsstyrelsen) background work in this area is incomplete, as they have not elucidated or examined what consequences the law will have for anyone other than children / adolescents, who are already not allowed to legally acquire/buy the products (the 18-year limit must be enforced).

The reason why this only applies to e-cigarettes/vape products (and possibly other low-risk products such as HnB and snus /chewing tobacco), and does not apply to tobacco cigarettes is that vape products also have a public health beneficial and positive effect, by having smokers replace all or part of their tobacco consumption with a low-risk alternative. Therefore, there is an unexplained negative consequence of the proposal to amend the law. In summary: Unlike cigarettes, e-cigarettes also has a positive side.

DADAFO's impact estimates are as follows:

- As 40 young people per day start smoking, and only approx. 8% of these young people (about 3) had e-cigarettes as their first nicotine-containing product, the legislation will have a maximum effect of approx. 1.200 children / young people per year.
- In Denmark (according to the study; Danes' Smoking Habits 2018⁵) approx. 260.000 adult e-cigarette consumers; of which approx. 78,000 completely got rid of the tobacco cigarettes/stopped smoking completely..

Positive and negative consequences for these two groups must be weighed against each other, so that the public health consequences have been elucidated. It is not enough just to point out that there is a negative consequence for a small group if the overall picture for public health is positive.

At the same time, we predict, based on market knowledge, that 90-95% of all e-cigarette specialty stores in Denmark will be forced to close before June 2021 (*Red: January 2022*), as their business is mainly driven by

https://www.sst.dk/-/media/Udgivelser/2019/Danskernes-rygevaner---aarsrapport-2018.ashx?la=da&hash=FDCC21DAE57E7D41
1AC3AD4E0F781BD7D425A488





profits from the sale of e-liquids with flavors. The last 5-10% of businesses will temporarily survive with the sale of e-cigarette equipment/hardware at a higher price than today. This is not long-term, as their competitiveness in relation to foreign business will be minimal.

Therefore, the sale of the products that today is primarily in specialty stores, will move to retail outlets, which will result in less control of sales to minors. In fact the opposite of the intention of the law. In retail stores, the dominant players are the tobacco industry, and it is doubtful whether products that are independent of the tobacco industry will survive in this space, let alone be allowed to be placed on the shelves of retail stores.

In this scenario, it is necessary to use the precautionary principle proportionally, as the EU definition describes. You must not <u>only</u> deal with a small part of the problem, but <u>all the consequences</u> must be taken into account. For the above, it may be that there is a positive effect of approx. 1.200 danish youth, but also that there is a negative effect on a large percentage of the approx. 260.000 danish adults who vape.

DADAFO estimates that there is a high risk that 10-25% of the vapers will return to smoking tobacco cigarettes due to lack of supply, and because the flavors that consumers are used and like using, are being banned. This means that the bill will have an overall negative public health consequence in relation to the status quo and therefore **cannot** overrule the TPD, or be argued to be necessary. We predict that the law will be withdrawn in the European Court of Justice, and overturned, for breach of the directive, if the bill as proposed in its current wording is adopted, without prior consultation with the European Commission.

The current legislation

The current law on electronic cigarettes etc. already creates such a tight regulation of products that can be marketed, and thus sold to consumers in Denmark, and further tightening is extremely unnecessary. Danish consumers are already suffering from a very sparse range of products, both hardware and e-liquids, as the costs of being able to market products in Denmark are among the highest in the EU / World. The sparse selection of e-liquids on sale in Denmark has a low potential for competition among brands, and thus also a restriction in available products. The Danish specialty stores have taken special care of the age control, and taking care of this guardian role with excellence, is our experience.

Legislation must be based on facts - and the evidence

"Law on electronic cigarettes, etc." has already been implemented – and it has formed the basis for the consumption pattern that the Danes have become accustomed to since 2016. It takes time before you can see some real and factual patterns in consumption. As mentioned, legislation already exists to restrict youth access to electronic cigarettes, etc. – and if this legislation was enforced, it should be sufficient to prevent youth from beginning to consume e-cigarettes. Furthermore, the parents also have a responsibility to their children until they turn legal, at the age of 18.

You could possibly consider a controversial solution; to make it completely illegal to possess e-cigarette products if you are under 18, thus allowing the Police to confiscate the products, just as is the case if young people illegally drive on moped without a driver's license and if they are not old enough.

Similarly, the sale of tobacco-free snus or tobacco products containing tobacco, such as snus, chewing





tobacco, tobacco cigarettes, pipe, cigar, cigarillos, etc. is already prohibited for children and adolescents under 18 years of age. Here, a ban, with the option of confiscation, could also be a solution.

A more realistic solution would be to allow only the marketing of e-liquids with flavors in specialty stores, and to narrow the range of flavors only in retail stores to tobacco and menthol. This solution is currently being proposed as a bill in New Zealand⁶. At the specialized stores you can at the same time introduce forced ID / age control, with the "3 strikes and you're out" solution that the bill already proposes. The problem in the retail stores is, that especially at peak hours at the checkout, it is easy to forget to check the customers' age / ID. Solutions such as age checks via Nets can solve this, but still have problems with young people being able to use their parents credit cards. This will not have a significant impact on the market, as most of the sales in Denmark are already in the specialty stores. Control of forced ID can thus also be minimized by the fact that the Danish Safety Technology Authority (Sikkerhedsstyrelsen) also checks this during their normal inspection visits.

Online stores should be able to display their products as e-cigarettes are not homogeneous products. Consumers should be familiar with the products they buy, otherwise it is a matter of "buying the cat in the bag". Mods / hardware are not nicotine-containing and comparable to battery cases, and hiding these products is simply harassing consumers.

E-cigarette products are not homogeneous but heterogeneous and therefore it is problematic to have an exhibition ban on the internet. In order for the consumer to be able to choose the "right" product for him / her, it is necessary to be able to assess the shape, appearance and functionality of the "hardware". However, we agree that an exhibit ban on e-liquids will not be of any significance to the consumer.

The side effect of the above is that consumers can at the same time get better information and guidance on their use of e-cigarettes and their potential smoking cessation, since the specialty shops usually have staff who are informed about the limitations and possibilities of the individual products, and can also inform about the optimal level of nicotine that the consumer can/should use in relation to his/her current consumption of cigarettes.

Further and unnecessary regulation will result in a greater degree of offense, people breaking the law – a law must be fair and logic, and not require victims among adult consumers who use the products legally in their successful smoking cessation.

The use of flavor in vapes/e-cigarettes

If you look at the smoking habits of the Danes (no matter how consistent it is), you can see that there is a large consumption of e-liquids with the taste of fruit, candy and cake. And since the market for youth is minimal, this consumption must be with adult vapers. Therefore, the whole argument that these flavors are only there to make children vape, is simply wrong. Thus, one can conclude that either the market is incompetent and has success despite incorrect marketing, or the whole basis of the presumption is wrong.

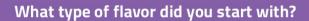
⁶ https://www.stuff.co.nz/national/health/119720489/new-vaping-law-bans-u18s-and-advertising

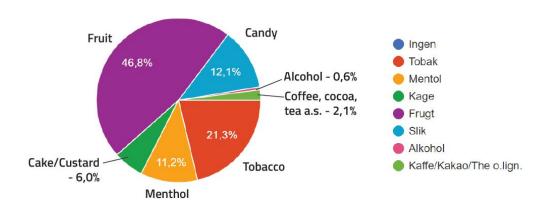




<u>DADAFO's own consumer survey</u>⁷, regarding the use of flavors in e-cigarettes shows that there is a clear tendency, as consumers of e-cigarettes move further and further away from smoking tobacco cigarettes/dual use - then the use of e-liquids with tobacco and menthol flavor becomes less frequent. The use of flavors <u>other</u> than tobacco and menthol thus prevails, to remove the association with tobacco cigarettes.

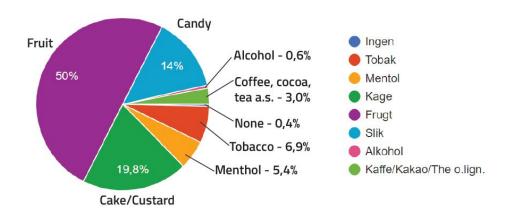
DADAFO conducted its own consumer survey in late 2019, and asked the Danish consumers of e-cigarettes, among other things. about which flavor(s) they used when they first started vaping - and which flavor(s) they were using now, or when they stopped vaping. There were 536 respondents.





As shown in the above chart, tobacco and menthol respectively. 21.3% and 11.2% (a total of 32.5%) preferred flavors in the beginning - as these flavors are well known, and since most people initially demand flavors they know from the common tobacco cigarettes.

What type of flavor do you use now or when you stopped vaping?



²https://dadafo.dk/wp-content/uploads/2020/04/DADAF0-E-cigarette-and-vaper-consumer-survey-2019-2020_EN.pdf

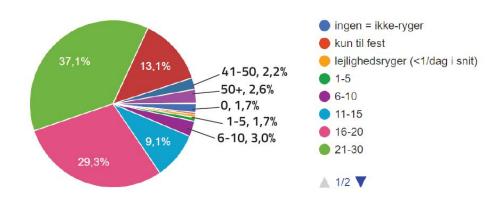




Gradually, the taste of consumers changes, so that only 6.9% prefer the taste of tobacco and 5.4% prefer the taste of menthol (a total of 12.3%). There is a percentage **reduction** of respectively. approx. 300% for tobacco flavor and approx. 200% for menthol flavor (total change in % from 32.5% to 12.3%)

The taste in e-vapor/e-liquids is therefore essential to making a successful smoking cessation and to replace the tobacco cigarettes completely with e-vapor. Most consumers can tell that they do not want to use tobacco flavor in their vapor, as it reminds them too much of "when they used to smoke" - and that they are afraid that just the taste of tobacco. will keep/retain them in the consumption of tobacco cigarettes, or that the taste of tobacco may cause them to not make a 100% successful smoking cessation/switch to the exclusive use of e-cigarettes as the preferred low-risk alternative to continued tobacco smoking.

How many tobacco cigarettes did you smoke per day, before you started vaping?



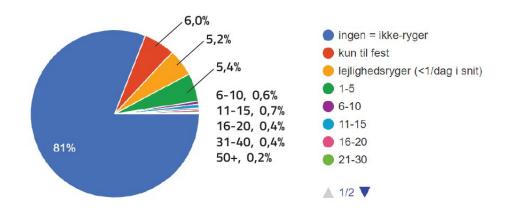
The majority of respondents smoked between 11 and 30 cigarettes a day before starting to vape, as shown in the chart above (37.1 + 29.3 + 9.1% = 75.5%)

As shown in the chart below, approx. 81% of the respondents who answered the questionnaire completely stopped smoking tobacco cigarettes, and the remainder are either party smokers, occasional smokers or smoke only 1–5 cigarettes a day. This large part of the population could possibly risk returning to tobacco smoking only if, for example, flavors in e-cigarettes were banned.





How many tobacco cigarettes do you smoke now?



A restriction on the selection of flavors and the prohibition on visible placement and display of electronic cigarettes and refill containers with and without nicotine at points of sale, including on the Internet, is likely to cause Danish consumers to increasingly try to:

- 1) buy products on the black market, or through friends
- 2) buy products in foreign webshops, through illegal imports from both EU and non-EU countries
- 3) buy products in border trade east and south of the Danish borders (Sweden and Germany)
- 4) increasingly mix the e-liquids privately, from the ingredients that are now available, with the risk of contamination and aroma content etc. which are not suitable for inhalation, e.g. lipids / oil-based aromas that under no circumstances should be used for inhalation
- 5) at worst go back to smoking cigarettes
- 6) and a few might find it possible to completely quit both e-cigarettes and tobacco cigarettes

There are many unintended consequences of the changes in the law that that is suggested. Prior to 2014, "Wild West conditions" prevailed in Denmark - that was the argument at the time for introducing regulation, and out of that came TPD and the Danish Law No. 426 - and after the introduction of both, Denmark has not seen cases of accidents / damage with the use of e-cigarette/vapor products. Consumers have adapted to a new pattern of consumption, and live with the slightly limited range, which is marketed in Denmark.

The proposed legislative amendments / additions will remove all control and overview of the situation in Denmark - and many consumers will return to a state like the one we had before 2014 - ie. buy e-liquids illegally incl. aromas, tanks, batteries, etc. from other EU Member States, which have not imposed the same severe restrictions that have been proposed in Denmark. You could say that the state after 2021 can be even worse than the conditions that were in 2014, since today there are far more people using e-cigarettes and are familiar with the product - so maybe the comparison with "**The roaring twenties**" is more appropriate, where the American mafia spent its heyday selling bootleg spirits to the dry USA during Prohibition?



"The Roaring Twenties" will have its premiere 100 years later ... in Denmark?8

With loss of control for the Danish Safety Technology Authority (Sikkerhedsstyrelsen) and the Danish Health Authority (Sundhedsstyrelsen) – they face an impossible task, as the products that they must control and regulate will be traded "underground" or via the black market. If this trend is to come to fruition, then the manpower and resources of Customs and Police must be significantly increased.

The basis for the proposed amendments and additions

The Minister for Health in fall of 2019 gave the Danish Health Authority (Sundhedsstyrelsen) a task to explain the development and the reason for the illness which was seen especially among young people in the United States in the fall of 2019. At this invitation, they published in October 2019 the memorandum "E-cigarettes and health" ⁹.

The memo is based, inter alia, on two major reports from respectively. USA, National Academies of Science, Engineering and Medicine (NASEM) – "Public Health Consequences of E-Cigarettes, January 2018" and England, Public Health England (PHE) – "Evidence review of e-cigarettes and heated tobacco products 2018: executive summary, March 2nd 2018". In addition to the two major reports, reference is made to scientific literature with emphasis on articles published after the two reports. Unfortunately, parts of this literature have not undergone a peer review, and therefore cannot be considered as valid evidence/facts, but solely as party submissions.

The trend in usage patterns, statistics, especially for children and adolescents when they came to e-cigarette products with or without nicotine, is not well documented in Denmark. A few studies have been carried out at intervals of several years, which may give some indications, but which do not provide a basis for certain conclusions. In particular, it should be noted that the figures for children and adolescents' smoking habits are stated with children as being 11-15 years old; and adults are listed as persons over the age of 15. Thus, adolescents aged 15-17 are included as adults, statistically speaking. This distorts the information and conclusions that could have been extracted from the information in the statistics.

By comparison, the English Department of Health,, is conducting extensive monthly updates on the development/statistics of consumption of tobacco and nicotine products – not only for children and adolescents, but also for the rest of the population. These studies are published publicly on the website "Smoking in England" – under the name "Smoking Toolkit Study, STS" – last updated 17.01.2020

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⁸ https://historienet.dk/samfund/amerikas-historie/forbudstiden-i-usa-nul-alkohol-gav-eksplosiv-kriminalitet

https://www.sst.dk/-/media/Udgivelser/2019/E-cigaretter/E-cigaretter-og-helbred-notat-okt-2019.ashx?la=da&hash=A30D04B 3D51EA6230EF5D9C75F21B0527971801B

http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx

https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review-of-e-cigarettes-and-heated-tobacco-products-2018-executive-summary

¹² http://www.smokinginengland.info/latest-statistics/

¹³ http://www.smokinginengland.info/





Similarly, Germany's Ministry of Health also carries out extensive statistics – via "DEBRA – Deutsche Befragung zum Rauchverhalten"¹⁴ – last updated 12.12.2019.

If the DHA (Sundhedsstyrelsen), for example, estimated to carry out the same thorough statistics, we could overall have a much clearer picture of the use of tobacco and nicotine products in Denmark, and with that statistics the legislators would also have a better tool and basis to legislate on.

The trend from both the English STS and the German DEBRA is that the number of vapers in general is currently declining – and especially the number of young vapers in respectively England and Germany are incredibly low. Most of the young people who were vaping had already initiated smoking tobacco cigarettes. There are astonishingly few who have started vaping, without having previously smoked tobacco cigarettes. And the number of persons that first started with e-cigarettes and then went on to tobacco smoking is vanishingly small, in both England and Germany.

Focus must be placed on the health of adult consumers, while enforcing the ban on the purchase of tobacco for children and adolescents. Adult consumers over the age of 18 are fully entitled to have their own lives and health, and if a (hopefully) larger portion chooses e-cigarettes as their alternative to tobacco smoking, then it is a major health benefit, both for the individual and for society as a whole.

Unfortunately, the background to the DHA's memo, clearly shows that there are not yet enough national data/statistics that can give a good enough overview of the situation in Denmark. Therefore, an evidence-based basis for additional restrictions on the marketing, sale and consumption of vaping products is not present. The DHA fears that the trend with many young people vaping in the US will find its way into Denmark. But one cannot use the political and health situation in the US to base legislation on in Denmark, as there is a wide difference in regulatory policy in the US, in terms of EU and Danish legislation.

Unfortunately, the debate among healthcare professionals, politicians, patient associations and the media has been about tobacco smoking and e-cigarettes being equally harmful to health, even though there is no evidence of that claim. We saw this with all clearness in the media, according to the many cases in the US, with primarily young people suffering lung damage after vaping illegal cannabis/THC-containing liquids that were "cut" / mixed with vitamin E acetate - which is a lipid/oil based product which must not be inhaled under any circumstances.

The US Center for Disease Control (CDC) has confirmed that the many cases of lung disease in Americans arose from the use of illegal THC pods containing vitamin E acetate¹⁵

The products that caused lung damage and deaths in the USes would be detected very quickly in the EU, due to the EU RAPEX warning system, which monitors the ingredients of the products notified via the EU-CEG portal and can quickly recall and issue warnings about exactly the products that have caused harm to the European population. However, if the products are not notified (ie. produced under controlled and legal conditions) the RAPEX system cannot be used as there is no knowledge of the ingredients, manufacturers,

¹⁴ https://debrastudy.wordpress.com/

¹⁵ https://www.cdc.gov/mmwr/volumes/69/wr/mm6903e2.htm





distributors and vendors of the products. Then we in the EU can end up in the same situation as in the US - with fatal consequences of uncontrolled production and associated distribution of illegal products.

Ultimately, the proposed amendments will result in deaths of otherwise safe consumers who may be forced to buy their nicotine-containing e-liquids on the black market if the only alternative is to go back to smoking cigarettes.

E-cigarettes have been on the market for so long that epidemiological data from reality far exceeds what is otherwise required to market similar medical products. Therefore, it is misleading to say that "you do not know anything" or that "you do not know long-term effects" – because you never do with new products, be it fizzy drinks/soda pop, vaccine or skateboards.

The problem from the consumer's point of view

As consumers of e-cigarettes e-vapor products, we MUST warn against the consequences of the proposed changes regarding legislation/regulation of e-vapor products with or without nicotine.

The legislative amendments were made without prior consultation with consumers, and thus also **DADAFO** - **Danish e-Damper Association**, which is the voice of Danish e-cigarette consumers. The proposed amendments testify that the persons who write and propose the major amendments do not have the sufficient knowledge about the products, as the text/wording of the amendments to the bill to special **Act No. 426 of 18/05/2016 (Electronic Cigarette Act etc.)** - largely demonstrates a lack of first-hand knowledge of both the products, their use and lack of knowledge of the population that uses the products.

There has been a huge lack of willingness to communicate, between the public authorities and the consumer organization / e-cigarette industry. The lack has been with the public authorities. In particular, the DHA (Sundhedsstyrelsen), which, despite several inquiries, first accepted a meeting with the participation of consumers and the e-cigarette industry on January 8th 2020. And at this meeting, it was very clear that the DHA's knowledge about e-vapor products (with or without nicotine) is extremely sparse and deficient. As an advisory body for the Ministry of Health and the Elderly in particular, it is extremely important that the DHA inform of **all available knowledge**, studies and research, and that they review this knowledge for conflicts of interest of all kinds, before drawing conclusions and making recommendations on an (unfortunately, as it turns out) too narrow and sparse basis.

¹⁶ https://www.retsinformation.dk/Forms/R0710.aspx?id=180119





Vincit omnia veritas - Truth overcomes everything

It has always been **DADAFO**'s attitude and hope that over time both authorities, health experts, politicians and the media would realize the major mistakes they have made in the treatment and perception of the alternative smokeless nicotine products. That the products are not a problem, but actually a solution to a problem – namely tobacco smoking. Tobacco smoking is not healthy – and e-cigarettes are not "healthy" either, but it is proven to be much less harmful to health than tobacco smoking.

But over time we have had to realize that the truth - factual science and evidence - is not being used as a basis for legislation and regulation in Denmark, let alone when the media has to elucidate the phenomenon "objectively".

When what we, as consumers openly see as a major advantage, is viewed as something negative – then the reaction from eg. consumers will always have to be that legislators, the media, government officials and others have no real and true intentions, and that public health is sacrificed in favor of financial dispositions and political negotiation.

For us consumers, it seems that the government has not been able to get a mandate and create a broad enough majority for sufficiently large rise in the tobacco prices, etc. and therefore chooses to include e-cigarettes in the amendments, because the government can then appear to be actionable (at least doing something). The adults and legal consumers, are sacrificed on the altar of youth, thus signaling that the adults life and health are obviously worth less than children and adolescents?

It further increases consumer frustrations when legislation is passed without listening to our knowledge and experience in the field. And especially when legislation is passed and recommendations are made on the basis of "feelings and sensations", without distinction of facts, science and empirical data.

It should also be noted that the proposals currently for amendments to the legislation on e-cigarettes/vapor products are as taken out of the tobacco industry's playbook/script, to conquer the market for smokeless nicotine products incl. products for evaporation.¹⁷

So consciously or unconsciously, if passed in its current wording, the bill is a direct helping hand to the tobacco industry, whose upcoming products are soon ready for retail sale. The tobacco industry's products are very likely to be "closed pod systems" that can easily replace the tobacco products on the shelves of kiosks, grocery stores and gas stations, etc. So far, only one product on the Danish market can call itself an "e-cigarette"; namely Vype ePen 3 from BAT (British American Tobacco) and then there is iQos from Phillip Morris, which is not an e-cigarette, however, as tobacco is heated and inhaled. Therefore, the product is called a "Heat Not Burn" product (HnB), and not an e-cigarette.

17

https://www.bat.com/group/sites/UK_9ZTFCM.nsf/vwPagesWebLive/D0BA7JRL/\$FILE/Step-Changing_New_Categories_-_A_very_significant_growth_opportunitv.pdf





So - whether the Ministry of Health or the politicians will or not - or realize it or not - they hand over the future market for smokeless nicotine products/enjoyment products - on a silver platter to the tobacco industry.

BAT (British American Tobacco) calls itself the "A very significant growth opportunity", and describes the entire course of their future strategy, with the attached link to their report. The report is updated on March 14, 2019 - and so far, the plan is running by the book!

The bill being consulted is written in a way that is directly in line with BAT's strategy:

- Moving e-vapor from specialty stores to retail stores
- Limited selection both of equipment and flavor variants
- Transition from more individually oriented and large e-cigarettes to small simple products
- Consolidation of e-vapor products from a wide range of independent producers to a few large companies (the tobacco industry manufacturers)

The tobacco industry, and in Denmark more specifically BAT, in other words become the big winners in this game. Roughly speaking, "The tobacco industry is getting a new market handed over by the state, as a thank you for long and faithful service in filling the tax departments money tank" (quote from e-cigarette retailer).



Excerpt from BAT's report "A very significant growth opportunity" - from March 14, 2019 - Fourth from the left is the product Vype ePen 3, which has been notified through the Danish Safety Technology Authority (Sikkerhedsstyrelsen) and is currently for sale in the Danish retail trade.





DADAFO In October 2019, released the information leaflet "12 good tips for smoke-free 2019", which gives good advice to especially lawmakers and officials on how legislation in this area should be tackled. The information leaflet was distributed to the members of the "Folketing" (The Danish parliament) and members of the Health Committee (Sundhedsudvalget), on a public consultation that took place on 24th of September 2019:

- 1. Raise the price of tobacco and give smokers better and easier access to low-risk alternatives
- 2. Set clear goals on how to get fewer smokers, for instance by taking a look at the "Smoking Toolkit Study" (STS) from the UK
- 3. Be sure to enforce the age limit and enforce the law strictly
- 4. It is the parents' responsibility to raise their children not the state's
- 5. Abolish retail marketing, but allow widespread marketing in specialty stores of e-vapor products
- 6. Branding and informing of e-vapor products for adult consumers who want a low-risk alternative
- 7. Non-smoking school hours in primary and secondary education
- 8. Ensure that more people are offered smoking cessation via the opportunity to switch to low-risk alternatives, including e-cigarettes
- 9. Provide subsidies for smokers who will try to replace tobacco with e-cigarettes/vapor products
- 10. Support existing legislation and optimize the use of legal products
- 11. Understand the importance of a wide range of flavors in smokeless tobacco and nicotine products
- 12. E-vapor/e-cigarettes cannot be covered by the Smoking Act. Vapor is NOT smoke



The folder can be downloaded - by clicking on the graphic above, or via link in footnote 17.

¹⁸ https://dadafo.dk/wp-content/uploads/2019/11/DADAF0_12_gode_r%C3%A5d_til_r%C3%B8gfrihed_2019_20191021.pdf



How large is the consumption of e-cigarettes in young people?

There <u>is a problem among children/adolescents</u> – but the problem is: TOBACCO CIGARETTE, and not e-cigarettes!

- E-cigarettes are mainly used by young people who already smoke tobacco cigarettes
- There is minimal "gateway" access to cigarettes from new nicotine products (no gateway)
- E-cigarettes are not "cool" among young people
- It is obvious that snus has growth with youth, since the introduction of more and more smoke-free schools
- If one looks at Norway/Sweden then it is clear that despite the same prevalence of nicotine consumption among young people as in Denmark, there is a fantastic low prevalence of smoking among young people in Norway and Sweden, and so all talk of a "gateway" is simply not objective

From the Danish "Think Tank" Monday Morning's report, February 2020: <u>"From the Marlboro man to the woman with the e-cigarette"</u>

Quote from page 28: "The young people know the new products and indicate that maybe snus or chewing tobacco can make you smoke less, but it is not very smart to chew tobacco - especially not among girls. But among a group of boys in particular, it is okay to chew some tobacco or use real snus imported from Sweden. E-cigarettes are certainly - still according to the young people - a smoking cessation drug, but otherwise even more dangerous than cigarettes and quite lame to look at - however, except for the new Juul, which is not yet available in Denmark. If you vape on something other than a Juul, it should be because you are about to stop. Otherwise you are really "lame" in the optics of the young people."

From the daily newspaper Jydske Vestkysten, 16.09.2018 - Danish young people: E-vaping is not hot!

Quote: "Kim Dabelstein Petersen, chairman of DADAFO, believes that a difference in youth culture is the reason: - Young people in Denmark simply think it is utter shite" he says.

According to the chairman, what he calls American hysteria around young vapers has helped provoke a "rebel" rise in consumption. He also refers to a 2016 EU directive that banned the marketing of e-vapor products and sales to minors in Europe.

According to Niels Them Kjær, project manager for tobacco prevention in the Danish Cancer Society, the directive has just dampened youth consumption in Denmark.

- It is my impression that we have seen a stagnation since the entry into force of the EU directive. However, our latest figures are from 2016, so it is not exactly known, he says."

The above quotes and conclusions are completely in line with the view we, as an association, together with the Danish Cancer Society, have previously referred to in the media, of the young people's perception of e-vapor products.





Survey of schoolchildren						
	Ever tried		Difference in %	Previous		Difference in %
	2014	2018		2014	2018	
Boys (age)						
11	3	2	-33%	2	<1>	-100%
13	11			11-7	5	-28.5%
15	33		30%-1.1	17	13	-23.5 %
Girls (age)						
11	1	1	-	1	<1	?
13	7	5	-28%	4	2	-50%
15	24	17	-29%	13	7	-46%

This also corresponds very well with the available statistical figures we have from the School Children Surveys from respectively 2014 and 2018 (see table above) – where the number of young people between 11 and 15 – who ever tried and the number who have used e-vapor in the last month has dropped dramatically. For girls in particular, consumption is approx. halved. We expect that the number of young people who have tried or often use e-cigarettes has further decreased since 2018 – and this could possibly be confirmed if the Danish Health Authority (Sundhedsstyrelsen) will soon publish their long awaited publication "Danes' Smoking Habits 2019".

The much-cited sample of the municipality of Copenhagen, which measured that 45% of pupils in the 9th grade had tried e-cigarettes, falls within the scope of the results in the School Children Survey of 2018 when correcting for the fact that young people in Copenhagen are more experimental than the national average.¹⁹

Links to statistics about young people / children's and adults' consumption of e-steam:

Health - "E-cigarettes and health, in October 2019"

Smoke Free Future Youth Survey 2017

Danish The Smoking 2018 - Annual Report

Danish The Smoking 2018 Method Memo

Danish The Smoking 2018 Cross tables All

National Institute of Public Health: School Child Survey 2014

Study: Danish National Institute for Public Health: School survey 2018

SmokelessTime - Smoking2018 - Copenhagen Municipality

Health and well-being in upper secondary education 2019

¹⁹ https://www.kk.dk/nyheder/naesten-hver-anden-elev-i-9-klasse-i-koebenhavn-har-proevet-e-cigaretter





On behalf of the Danish e-cigarette consumer, **DADAFO** is always available and with all the knowledge we have for an open dialogue about the future of e-cigarettes and vapor products, as a far less harmful alternative compared to smoking cigarettes.

As a starting point, **DADAFO** advocates that e-cigarettes are exclusively a product that can be used by smokers and former smokers to become smoke-free. It is not a product that children/youth or never-smokers/never-vapers should use.

And as an association, **DADAFO** asks the politicians to "think about the children" - ie. make sure their parents live longer, by having many different opportunities to become smoke-free, thus increasing their quality of life and life expectancy - so they can stay with their children for as long as possible.

On behalf of the association's members, the board of DADAFO and the Danish vapers...

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Who is DADAFO

DADAFO - Danish Vapers Association, is an independent, non-profit consumer organization run by members/consumers. The board is elected by the members and the association is run for the membership fees and the consumers voluntary donations. There are no financial connections to either the tobacco, pharmaceutical or e-cigarette/e-vapor industries. All work in the association is done voluntarily on a pro bono basis.

DADAFO speaks on behalf of the Danish vapers, as well as the smokers who in the future are expected to want to use an e-product as an alternative to smoking tobacco - or as part of a smoking cessation.

DADAFO currently has over 3.100 registered and dedicated members, all of whom are over 18 - which is a requirement for membership of the association. The median age of the association members is approx. 40-42 years. The members of DADAFO come from all parts of the country, and the state community.

DADAFO is part of a larger international consumer community; **INNCO**, **The International Network of Nicotine Consumer Organizations** – which, through information and knowledge sharing, tries to put tobacco harm reduction, THR, on the global political agenda.

DADAFO is part of a larger European consumer community, <u>ETHRA - European Tobacco Harm Reduction</u> <u>Advocates</u>, which, through information and knowledge sharing, tries to put tobacco harm reduction, THR, on the European political agenda.

DADAFO is part of a larger Nordic consumer community, <u>NNTHR - Nordic Network on Tobacco Harm</u> <u>Reduction - CSO-NGO</u>, which through information and knowledge sharing, tries to put tobacco harm reduction, THR, on the Nordic political agenda.

DADAFO conducts nonprofit lobbying and information work, and actively participates in information work, standardization work through Danish Standard, CEN and ISO.

DADAFO participates in international conferences on health promotion, tobacco harm reduction and the use of alternative nicotine products as a substitute for the tobacco products.

DADAFO is always available for a developing and mutually informative dialogue – and you can always contact us with any questions – by visiting our website.

DADAFO as a consumer organization, advocates that the market for e-cigarettes and e-vapor products must of course be regulated - so that we as consumers can be sure that the equipment we buy is as safe as possible and that the liquids we buy are as good, clean and of the highest quality possible. But regulation/legislation must also be proportionate, to ensure that it is not easier or cheaper to choose tobacco cigarettes rather than e-cigarettes.





DADAFO as a consumer organization, is in favor of setting an age limit of 18 years, as adopted by law. We are well aware that there are already vapers under the age of 18, and setting an age limit makes it easier for politicians to argue that e-vapor products are primarily for use by adults trying to make something good for their health, by replacing the tobacco with a far less harmful alternative.

DADAFO as a consumer organization, does **NOT** advocate that e-cigarettes/e-vapor products should be equated/conflated with smoking – and thus covered by the "Smoke-free Environment Act". To date, there is **NO** scientific basis for equating vapor and smoke, as all studies and tests conducted by the chemical composition of the vapor shows, that there are no hazardous substances in the vapor that is exhaled in sufficient quantities to create any health damage if staying with or standing right next to someone vaping. The smell/scent of the vapor can of course be a nuisance to someone – just like poor body hygiene, excessive use of perfume etc. can be a nuisance to someone – not saying that just because something can irritate you, it is automatically a health risk.

DADAFO as a consumer organization, does **NOT** endorse the adoption of a total advertising ban on e-cigarette related products. From a health perspective, all consumers of tobacco products should be made aware that today there is a far less harmful alternative – by which many can completely replace tobacco smoking by switching completely to vaping.

DADAFO as a consumer organization, does **NOT** advocate a total export and import ban on goods from the other EU Member States. The "e-cigarette law" does not prohibit direct export and import, but makes the opportunity extremely expensive for manufacturers outside Denmark. If a manufacturer wants to sell its products (possibly via webshops located in other EU countries) – then the vendor/manufacturer must apply/notify his products to the Danish Safety Technology Authority, after paying some very high notification fees that do not meet the requirement via the EU on the free accessibility of goods across EU borders. If a Danish company wants to market/sell its products in another EU country, the products may have to also be notified to the country's local authority before a sale/export can be carried out legally.

Unfortunately, DADAFO sees a possibility that the only products that can be legalized through the bill will be products that must meet such high requirements for leaking safety and a filling mechanism that also ensures against contact with the nicotine-containing liquid - that the only products that will be allowed will become the so-called cig-a-likes: E-cigarettes that look like traditional cigarettes, and as most experienced vapers have only used for a very short period, as the products are too inefficient and too poor in practical use.

DADAFO is an association for all e-cigarette consumers - and you can join the association by registering on our website: www.dadafo.dk/medlemskab

A basic membership is free - and you can become a full member for only DKK 120 per year. As a vendor or employee in a vape store, you can sign up for a support membership, also for DKK 120 per. year. As a support member, however, you have no right to vote or representation on the association's board or committees.