English translation of DADAFO (Danish Vapers Association) short contribution

To the European Commission

Regarding notification 2020/0228 / DK - S00S / Bill amending the Act on the ban on tobacco advertising etc., Act on tobacco products etc., Act on electronic cigarettes etc. and various other acts (Implementation of the national action plan against smoking by children and young people)

As a follow-up to the recently submitted notification regarding the Danish proposal for the national action plan against tobacco, with a special focus on e-cigarettes / vaping - the Danish Vapers Association, on behalf of the Danish consumers of e-cigarettes / vapes, will reply and comment on the notification from the Danish Business Authority and the Ministry of Health and the Elderly to the Commission.

Are the changes in the law creating better public health, or is the law worsening the health of e-cigarette consumers?

The focus of the amendments to existing legislation should address how public health as a whole is affected by the bill. Nowhere in the notification from the Danish Business Authority and the Ministry of Health and the Elderly has an impact assessment been carried out of the proposed legislative changes and tightenings, as required in any EU process, and according to Directive 2014/40/EU.

It is our opinion that the intervention, which is primarily focused on preventing children and young people from accessing all nicotine-containing products (except drug-approved nicotine replacement products), has a disproportionate bias / distortion in relation to adult consumers of vaping products. Consumers who have succeeded in becoming either completely or partially smoke-free, without the support or help of public authorities. In our opinion, the bill will make it more difficult for adult smokers to get out of their harmful consumption of primarily tobacco cigarettes - if the bill regarding e-cigarettes is adopted in its current wording.

The many amendments were sent for public consultation, and DADAFO submitted its consultation response regarding the bill amending Act no. 426, the Electronic Cigarettes Act, etc. on 21.02.2020.

DADAFO's comments and the original consultation response, are attached to this letter as a separate file, in both <u>Danish (Appendix 01)</u> and <u>English (Appendix 02)</u>, and will in principle contain all the arguments that the consumers' association will present to the Commission, as a comment to the notification from the Danish Business Authority and the Ministry of Health and the Elderly in Denmark.

"Guilty until proven not guilty"

In particular, we refer to the incorrect use of the "precautionary principle", which in Denmark means that e.g. vaping is found guilty until proven not guilty. Unfortunately, it seems that The Ministry of Health is not particularly interested in investigating possible good or bad health

consequences due to the use of e-cigarettes / vaping. It is our argument that the benefits of replacing tobacco cigarettes with vaping without a doubt and far outweigh any disadvantages.

Listen to the consumers!

the effects of nicotine.

The notification text sent to the Commission states that either the Ministry of Health and the Elderly did not read our consultation response, or they chose to ignore our (consumers) arguments before the final bill was sent to the Commission for notification. The Ministry has not taken into account the comments of consumers or retailers / manufacturers, on the amendments made to the law.

The proposal for changes to the law has not yet been through the parliamentary deliberations in the Danish Folketing, which we find strange.

We also find it strange that the government and its support parties want to introduce new and further restrictive legislation for e-cigarettes, at the same time as the Commission has launched a study on the European e-cigarette market in particular. Before the Commission has formed an overview of the current market as well as the current legislation / regulation in the individual member states, Denmark has decided to propose further restrictions, without looking at whether the existing legislation from 2014/2016 has worked as intended. It turns out that the Danish "Act on electronic cigarettes, etc." has actually been effective, and perhaps even too effective, as the number of young people (under 18) and adult smokers starting or switching to vaping has declined in recent years.

Legislation on a scientific, statistical and legal basis

The Commission can neither must nor should allow the proposed amendments to the Danish national Act no. 426, Act on electronic cigarettes, etc. - as there is simply no scientific, statistical or legal basis for making such drastic changes to a law that works as intended - without leading to a series of unintended consequences for several sections of the population - see DADAFO's initial consultation response.

Lack of risk assessment and impact assessments can prove fatal / catastrophic Nowhere in the notification or in the bill / amendment is there mentioned a comparison in risk between smoking tobacco cigarettes and vaping. There is a lack of a risk assessment and an analysis of the overall harmfulness of the various nicotine-containing products to consumers. If A is 95% less harmful than B, consumers should be advised to switch to A. Also, and especially, in the longer term, there can no longer be any doubt that low-risk alternatives to continued consumption of tobacco cigarettes must be to recommend the products with far lower health risks for smokers, who either cannot or will not stop enjoying

Children and young people in Denmark do not use e-cigarettes to a worrying degree Via an inquiry with the Danish Safety Technology Authority, which handles supervision of e.g. specialty stores that sell e-cigarettes and e-liquids, we have been informed that at the moment via their supervision, there do NOT appear to be illegal sale of nicotine-containing products to young people under 18 from the specialty stores. Through their control of the

specialty stores, the Danish Safety Technology Authority has not found cases of illegal sale of products to children / young people under the age of 18 for a long period. The industry has taken their responsibilities seriously, and is making sure to enforce the sales ban for young people under 18 years of age.

We want to make it very clear that DADAFO prefers to see **no one** start smoking or vaping; neither young nor old, unless they are already smokers trying to quit tobacco. But we would like as many smokers as possible to have the opportunity to quit again. In our view, vaping is exclusively a product for smokers who want to try to get rid of tobacco cigarettes.

Restrictions on flavors

Additional restrictions on a product that already complies with existing legislation, without giving rise to major concerns, seem to us to be superfluous and unnecessary legislation. In Denmark, we are dealing with a product that has already been subject to strict restrictions in terms of price, selection, innovation - and further restrictions will lead to some severe unintended consequences.

To protect part of the population (young people under the age of 18), the adult consumers are sacrificed, as most of them use e-liquids with a taste that is NOT tobacco or menthol. In fact, it turns out that some actually start vaping with a tobacco or menthol flavor, but the majority choose to drop the flavor of tobacco, as for many it is too reminiscent of the "flavor" that they are trying to get away from.

And here the taste of e.g. strawberries, peaches, watermelons, caramel or licorice are actually an important factor that as many smokers as possible can in a short time call themselves ex-smokers. It should be recommended to have as wide and varied a selection of different types of tobacco harm reduction products as possible, if one wants to produce a rapid reduction in smoking prevalence. In contrast, restrictions and bans will simply result in consumers feeling criminalized and will eventually either start smoking again, or be relegated to a black market, to buy the products they demand (e-liquids with flavor, other than tobacco and menthol).

The Commission must be aware of its responsibilities

If the Commission allows the Danish government, represented by the Minister of Health and the Elderly, to make drastic changes in the legislation on e-cigarettes and liquids for vaping, this will in all probability lead to that other EU countries may follow, despite the fact that, as mentioned, there is no scientific, statistical or legal evidence that the proposed restrictions will lead to a reduction in the number of children / young people trying to use an e-cigarette. Especially not as the number of children and young people who vape regularly, or have tried vaping, is vanishingly low.

Danish consumers will therefore ask the Commission to listen to the vast knowledge that the consumers have. If the number of smokers is to be reduced quickly and efficiently, e-liquids with flavors other than tobacco and menthol should remain legal; and e-liquids and equipment must not be disproportionate to taxes and duties. If it is easier and cheaper to buy a pack of tobacco cigarettes, then a predominant part of the population will make "the easy

choice". Especially when there is a total ban on informing the population that there are in fact low-risk alternatives to smoking tobacco, e.g. e-steam, snus, tobacco-free snus, etc.

To the European Commission

Regarding notification 2020/0228 / DK - S00S / Bill amending the Act on the ban on tobacco advertising etc., Act on tobacco products etc., Act on electronic cigarettes etc. and various other acts (Implementation of the national action plan against smoking by children and young people)

As a follow-up to the recently submitted notification regarding the Danish proposal for the national action plan against tobacco, with a special focus on e-cigarettes / vaping - the Danish Vapers Association, on behalf of the Danish consumers of e-cigarettes / vapes, will reply and comment on the notification from the Danish Business Authority and the Ministry of Health and the Elderly to the Commission.

Are the changes in the law creating better public health, or is the law worsening the health of e-cigarette consumers?

The focus of the amendments to existing legislation should address how public health as a whole is affected by the bill. Nowhere in the notification from the Danish Business Authority and the Ministry of Health and the Elderly has an impact assessment been carried out of the proposed legislative changes and tightenings, as required in any EU process, and according to Directive 2014/40/EU.

It is our opinion that the intervention, which is primarily focused on preventing children and young people from accessing all nicotine-containing products (except drug-approved nicotine replacement products), has a disproportionate bias / distortion in relation to adult consumers of vaping products. Consumers who have succeeded in becoming either completely or partially smoke-free, without the support or help of public authorities. In our opinion, the bill will make it more difficult for adult smokers to get out of their harmful consumption of primarily tobacco cigarettes - if the bill regarding e-cigarettes is adopted in its current wording.

The many amendments were sent for public consultation, and DADAFO submitted its consultation response regarding the bill amending Act no. 426, the Electronic Cigarettes Act, etc. on 21.02.2020.

DADAFO's comments and the original consultation response, are attached to this letter as a separate file, in both <u>Danish (Appendix 01)</u> and <u>English (Appendix 02)</u>, and will in principle contain all the arguments that the consumers' association will present to the Commission, as a comment to the notification from the Danish Business Authority and the Ministry of Health and the Elderly in Denmark.

"Guilty until proven not guilty"

In particular, we refer to the incorrect use of the "precautionary principle", which in Denmark means that e.g. vaping is found guilty until proven not guilty. Unfortunately, it seems that The Ministry of Health is not particularly interested in investigating possible good or bad health consequences due to the use of e-cigarettes / vaping. It is our

argument that the benefits of replacing tobacco cigarettes with vaping without a doubt and far outweigh any disadvantages.

Listen to the consumers!

The notification text sent to the Commission states that either the Ministry of Health and the Elderly did not read our consultation response, or they chose to ignore our (consumers) arguments before the final bill was sent to the Commission for notification. The Ministry has not taken into account the comments of consumers or retailers / manufacturers, on the amendments made to the law.

The proposal for changes to the law has not yet been through the parliamentary deliberations in the Danish Folketing, which we find strange.

We also find it strange that the government and its support parties want to introduce new and further restrictive legislation for e-cigarettes, at the same time as the Commission has launched a study on the European e-cigarette market in particular. Before the Commission has formed an overview of the current market as well as the current legislation / regulation in the individual member states, Denmark has decided to propose further restrictions, without looking at whether the existing legislation from 2014/2016 has worked as intended. It turns out that the Danish "Act on electronic cigarettes, etc." has actually been effective, and perhaps even too effective, as the number of young people (under 18) and adult smokers starting or switching to vaping has declined in recent years.

Legislation on a scientific, statistical and legal basis

The Commission can neither must nor should allow the proposed amendments to the Danish national Act no. 426, Act on electronic cigarettes, etc. - as there is simply no scientific, statistical or legal basis for making such drastic changes to a law that works as intended - without leading to a series of unintended consequences for several sections of the population - see DADAFO's initial consultation response.

Lack of risk assessment and impact assessments can prove fatal / catastrophic Nowhere in the notification or in the bill / amendment is there mentioned a comparison

Nowhere in the notification or in the bill / amendment is there mentioned a comparison in risk between smoking tobacco cigarettes and vaping. There is a lack of a risk assessment and an analysis of the overall harmfulness of the various nicotine-containing products to consumers. If A is 95% less harmful than B, consumers should be advised to switch to A. Also, and especially, in the longer term, there can no longer be any doubt that low-risk alternatives to continued consumption of tobacco cigarettes must be to recommend the products with far lower health risks for smokers, who either cannot or will not stop enjoying the effects of nicotine.

Children and young people in Denmark do not use e-cigarettes to a worrying degree

Via an inquiry with the Danish Safety Technology Authority, which handles supervision of e.g. specialty stores that sell e-cigarettes and e-liquids, we have been informed that at the moment via their supervision, there do NOT appear to be illegal sale of

nicotine-containing products to young people under 18 from the specialty stores. Through their control of the specialty stores, the Danish Safety Technology Authority has not found cases of illegal sale of products to children / young people under the age of 18 for a long period. The industry has taken their responsibilities seriously, and is making sure to enforce the sales ban for young people under 18 years of age.

We want to make it very clear that DADAFO prefers to see **no one** start smoking or vaping; neither young nor old, unless they are already smokers trying to quit tobacco. But we would like as many smokers as possible to have the opportunity to quit again. In our view, vaping is exclusively a product for smokers who want to try to get rid of tobacco cigarettes.

Restrictions on flavors

Additional restrictions on a product that already complies with existing legislation, without giving rise to major concerns, seem to us to be superfluous and unnecessary legislation. In Denmark, we are dealing with a product that has already been subject to strict restrictions in terms of price, selection, innovation - and further restrictions will lead to some severe unintended consequences.

To protect part of the population (young people under the age of 18), the adult consumers are sacrificed, as most of them use e-liquids with a taste that is NOT tobacco or menthol. In fact, it turns out that some actually start steaming with a tobacco or menthol flavor, but the majority choose to drop the flavor of tobacco, as for many it is too reminiscent of the "flavor" that they are trying to get away from.

And here the taste of e.g. strawberries, peaches, watermelons, caramel or licorice are actually an important factor that as many smokers as possible can in a short time call themselves ex-smokers. It should be recommended to have as wide and varied a selection of different types of tobacco harm reduction products as possible, if one wants to produce a rapid reduction in smoking prevalence. In contrast, restrictions and bans will simply result in consumers feeling criminalized and will eventually either start smoking again, or be relegated to a black market, to buy the products they demand (e-liquids with flavor, other than tobacco and menthol).

The Commission must be aware of its responsibilities

If the Commission allows the Danish government, represented by the Minister of Health and the Elderly, to make drastic changes in the legislation on e-cigarettes and liquids for vaping, this will in all probability lead to that other EU countries may follow, despite the fact that, as mentioned, there is no scientific, statistical or legal evidence that the proposed restrictions will lead to a reduction in the number of children / young people trying to use an e-cigarette. Especially not as the number of children and young people who vape regularly, or have tried vaping, is vanishingly low.

Danish consumers will therefore ask the Commission to listen to the vast knowledge that the consumers have. If the number of smokers is to be reduced quickly and

efficiently, e-liquids with flavors other than tobacco and menthol should remain legal; and e-liquids and equipment must not be disproportionate to taxes and duties. If it is easier and cheaper to buy a pack of tobacco cigarettes, then a predominant part of the population will make "the easy choice". Especially when there is a total ban on informing the population that there are in fact low-risk alternatives to smoking tobacco, e.g. e-steam, snus, tobacco-free snus, etc.