

8 September 2016

Submission on Policy Options for the Regulation of Electronic Cigarettes
Ministry of Health
PO Box 5013
Wellington

Regulation of e-cigarettes

The work of the New Zealand Drug Foundation (the Foundation) is focussed on advancing an evidence-based approach to shaping policy aimed at reducing drug-related harm. As such, we are pleased to make a submission on the Ministry of Health's (the Ministry's) consultation document *Policy Options for the Regulation of Electronic Cigarettes* (the consultation paper). The Foundation welcomes the Ministry of Health's proposal to make e-cigarettes legally available subject to controls and consultation. We support the creation of an agile regulatory regime which reflects the principles of harm reduction and prevention, and we do not consider the Smoke-free Environments Act 1990 (SFEA) to be an ideal vehicle for this regulation. As with all policy, regulation should be sensitive to risk profile and context. Accordingly, a stand-alone statute seems more appropriate. Certainly, the historical decision to include herbal cigarettes under the SFEA was, in the Foundation's opinion, a very clumsy approach. However, in the absence of an opportunity to establish such a statute, we support the use of the SFEA as a vehicle for regulation.

Included in this submission is an overview of the key issues and evidence surrounding E-cigarettes, as well as our response to the key consultation questions proposed in the consultation paper.

E-cigarettes: Issues and evidence

The Foundation is aware that the international tobacco control NGO community is divided on the issue of e-cigarettes and that the debate is often 'heated'. In developing our submission, we decided to present our thinking on some of the concerns that have been raised and undertook a focussed review of the available evidence to inform that thinking. This is presented below.

Issue: Whilst there is scientific consensus that e-cigarettes are significantly less harmful than tobacco cigarettes, their potential harm is still not fully understood

Evidence: The Public Health England-commissioned report *E-Cigarettes: an evidence update* found that e-cigarettes are less harmful than tobacco cigarettes.¹ This has been supported

¹ LS Brose, R. Calder, A McNeill, SC Hitchman, P. Hajek, H. McRobbie. "E-cigarettes: an evidence update. A report commissioned by Public Health England", *Public Health England* (2015).

by research internationally,² and there is clear consensus that e-cigarettes offer a safer alternative to smoking. However, there are a number of known and unknown risks associated with e-cigarettes. FDA chemical analysis has detected the carcinogen tobacco-specific nitrosamines (TSNAs) in e-cigarettes of similar levels to other nicotine replacement products³ (1800 times less than tobacco cigarettes)^{4,5}. Nicotine itself is an addictive, psychoactive drug with the potential to be lethal in large doses. These potential risks are shared with other nicotine-containing products, and can be mitigated through similar controls to nicotine content. Whilst e-cigarettes are free from the vast majority of the harmful chemicals found in tobacco smoke,⁷ they have their own chemical composition and relatively little is known about the effects of e-cigarette liquid through vaping. For example, the safety of flavonoids in food consumption has been established, although the long term impact of their inhalation is unknown.

E-cigarette liquid usually contains propylene glycol and glycerol. Thermal degradation of these compounds, such as that caused by the heating of e-cigarettes, can cause them to emit toxins. Testing of 12 brands of e-cigarettes in 2013 detected low levels of the carcinogens formaldehyde and acetaldehyde (otherwise known as ethanal). These toxins were present at levels of up to 450 times less than that in tobacco cigarettes, although higher than that detected in nicotine inhalers.⁸ Long-term exposure to formaldehyde at certain levels, such as through occupational exposure, has been linked to cancer.⁹ According to the Centres for Disease Control and Prevention, the inhalation of ethylene glycol is unlikely to cause systematic toxicity, although it may cause eye and respiratory tract irritation.¹⁰ The 2014 Cochrane Review *Electronic Cigarettes for smoking cessation and reduction* (The Cochrane Report) found no serious adverse effects which could be plausibly related to e-cigarette use, however it is important to note that this report included a small number of trials. (The Cochrane Report is explained more fully under the below heading “E-cigarettes offer a less harmful alternative to tobacco smoking for cigarette users.”).

A key limitation of this research is the rate of e-cigarette product evolution. The speed of e-cigarettes’ entry into the market, and of their product innovation, has exceeded the ability of research to provide comprehensive evidence on their health impact, particularly from their long-term use. The messaging and regulation surrounding e-cigarettes needs to be agile, sensitive to this uncertainty, and responsive to new findings and innovation.

² Konstantinos E. Farsalinos and Riccardo Polosa, “Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review”, *Therapeutic Advances in Drug Safety* 5, no 2 (2014)

³ Z. Cahn and M. Siegel “Electronic cigarettes as a harm reduction strategy for tobacco control: a step forward or a repeat of past mistakes” (2011) *Public Health Policy* 32, pp.16-31.

⁴ Ibid.

⁵ H. Kim and H. Shin, “Determination of tobacco-specific nitrosamines in replacement liquids of electronic cigarettes by liquid chromatography-tandem mass spectrometry” *J Chromatogr A* (2013): 1291 pp. 48-55.

⁶ M. Laugesen Ruyan E-cigarette Bench-top tests. Society for Research on Nicotine and Tobacco (SRNT) Dublin, Poster 5-11. (2009) <http://www.healthnz.co.nz/RuyanCartridgeReport30-Oct-08.pdf> (Accessed: 18 November 2013).

⁷ Farsalinos and Polosa, *Safety Evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review*, p 73.

⁸ M. Goniewicz, J Knysak and M. Gawron, L. Kosmider, A. Sobczak and J. Kurek “Levels of selected carcinogens and toxicants in vapour from electronic cigarettes” *Tob control* (Published online: 6 March 2013).DOI: 10.1136/tobaccocontrol-2012-050859.

⁹National Cancer Institute “A fact sheet that discussed formaldehyde and its possible association with cancer” <http://www.cancer.gov/about-cancer/causes-prevention/risk/substances/formaldehyde/formaldehyde-fact-sheet>; (accessed August 31 2016)

¹⁰ “Ethylene Glycol: Systemic Agent”, Centres for Disease Control and Prevention, National Institute for Occupational Safety and Health http://www.cdc.gov/niosh/ershdb/emergencypersoncard_29750031.html (accessed August 31 2016)

Issue: E-cigarettes offer a less harmful alternative to tobacco smoking for cigarette users. However, there is limited evidence on the effectiveness of e-cigarettes in reducing or replacing smoking habits

Evidence: E-cigarettes offer a preferable alternative to smoking tobacco. In its report *Nicotine without smoke: Tobacco harm reduction*, the Royal College of Physicians concludes that a complete switch to e-cigarettes has the significant potential to prevent death and disability caused by smoking.¹¹ However, there has been relatively little research into the effectiveness of e-cigarettes for smoking reduction and cessation. The 2015 Public Health England report *E-cigarettes: an evidence update* reviewed studies undertaken into the effectiveness of e-cigarettes for smoking cessation, and supports their role in aiding smoking cessation. One of the studies reviewed (*An eight week Flemish study with six month follow up on smoking reduction, craving and experience benefits and complaints*)¹² involved 48 smokers who did not want to quit, randomised to e-cigarettes or no e-cigarettes. The first group received the e-cigarettes with training on how to use them but no encouragement to quit. After eight weeks 34% of those who received the e-cigarettes had quit smoking compared with 0% of the participants who had not. The first group also showed significantly higher signs of smoking reduction. At the eight week point in the trial the control group were given e-cigarettes, with no instructions. After a further eight weeks and at the conclusion of the study, 25% of that control group had quit smoking and 19% of the first group to receive e-cigarettes had quit.¹³

These findings are supported by the Cochrane Report, which found that e-cigarettes containing nicotine appear to help smokers quit. This report was based on data from two completed Randomised Control Trials (RCTs), nine ongoing RCTs, and 11 cohort studies, with a follow-up of at least 6 months.¹⁴ In two RCTs, a combined sample size of 662 current smokers were randomised to nicotine containing e-cigarettes or a placebo (non-nicotine containing e-cigarettes). The studies measured smoking abstinence (defined as continuous cessation for at least 6 months subject to biochemical validation) and smoking reduction (defined as a reduction in consumption of at least 50%). These studies found that a higher number of people were able to reduce cigarette consumption with nicotine containing e-cigarettes than with the placebo (36% versus 27%). E-cigarettes were also more successful in aiding smoking reduction than nicotine patches (61% versus 44%).¹⁵ Participants using nicotine containing e-cigarettes were also more likely to have abstained from smoking for at least six months than those who used the placebo.¹⁶

¹¹ Royal College of Physicians “Nicotine without smoke: Tobacco harm reduction” London: Royal College of Physicians. (April 2016) <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0> (accessed 1 September 2016)

¹² K. Adriaens, et al “Effectiveness of the electronic cigarette: an eight week Flemish study with six month follow-up on smoking reduction, craving and experienced benefits and complaints” *Int J Environ Res Public Health* (2014) 11, no. 11 : pp11220-48.

¹³ Brose et al. *E-cigarettes: an evidence update*, p 47.

¹⁴ Note: These completed and ongoing studies were selected from a search of the Cochrane Tobacco Addiction Groups Trials Register, the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, Embase and two other databases for relevant records. This found 600 records of which 29 were included in the report (11 cohort studies, two RCTs and nine ongoing trials).

¹⁵ Hayden McRobbie, Chris Bullen, Jamie Hartmann-Boyce and Peter Hajek “Electronic cigarettes for smoking cessation and reduction (Review)” *Cochrane Database of Systematic Reviews* (2014): 12, no. CD010216.

<http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD010216.pub2/abstract;jsessionid=75039E9B2DBA77E31DFD310DC7EB589C.f04t01>;

¹⁶ Note: the quality of evidence from the Cochrane Report was rated as ‘low’ or ‘very low’ by their internal GRADE system, given the small number of trials. A ‘low’ grade means that further research is likely to have an important impact on confidence in the estimated effect, and a ‘very low’ grade suggests uncertainty about the estimate.

Issue: There is a perceived risk that e-cigarettes may increase rates of tobacco smoking by providing a ‘gateway’ for non-users and by normalising or entrenching smoking behaviours

Evidence: Whilst e-cigarettes are a safer alternative to tobacco smoking, there is a perceived potential risk that e-cigarettes may increase the uptake of smoking by acting as a ‘gateway’. There is little evidence on whether or not vaping leads to smoking, or normalises smoking behaviours.¹⁷ The appearance of e-cigarettes has evolved to look less and less like traditional cigarettes, and product design increasingly differentiates e-cigarettes from tobacco cigarettes. E-cigarettes appear to be marketed as an alternative to tobacco smoking, rather than seeking to ‘re-normalise’ traditional tobacco smoking practise.

However, many of the features which distinguish e-cigarettes have also been identified as having the potential to increase uptake of vaping from non-smokers who may perceive it as safe practice. In particular, flavours such as mint, chocolate and strawberry have been identified as targeting young people. There is not sufficient evidence to support or dismiss the risk of e-cigarette uptake from non-users, and in particular, young people.

There is one published nationally representative survey of children’s e-cigarette use in the United Kingdom. This was conducted in 2013 and included a sample size of 2,178 11-18 year olds from Great Britain. 99% of those who reported never having smoked also reported never having used e-cigarettes. None of these non-smokers reported using e-cigarettes more than once a month or week.¹⁸ This study is currently being replicated and is subject to the limitation of self-reporting, but its findings suggest there is a very limited effect of vaping uptake among young non-smokers. It is not known whether or not that 1% of young non-smokers who tried e-cigarettes once, went on to smoke cigarettes.

A US study uses a larger sample size of children from high schools and middle schools (aged 11-18 years) from all 50 states (18,866 children in 2011 and 24,658 in 2012). This study compared the behaviour of subjects between each year and found an increase in the number of subjects who had ever used e-cigarettes from 3% in 2011 to 7% in 2012. It also found an increase in those who used e-cigarettes more than once a month from 1% to 2%. The 2012 survey asked about the co-use of e-cigarettes with tobacco cigarettes and found that 76% of those who had ever tried e-cigarettes were current smokers. E-cigarette usage of more than once every 30 days was associated with having smoked tobacco cigarettes or current use of tobacco cigarettes.¹⁹ Reflective of more recent findings, the 2015 Public Health England report concluded around two thirds of e-cigarette users also smoke.²⁰

Whilst e-cigarette use in children and young people under the age of eighteen is increasing, their use tends to trend towards tobacco cigarette users, rather than those who have never, or do not, smoke tobacco cigarettes. Given the low uptake amongst non-smokers, the risk of e-cigarettes acting as a ‘gateway’ to tobacco cigarettes appears to be low, according to current research.

¹⁷ Brose et al, *E-cigarettes: and evidence update*, discussion on ‘gateway’ hypothesis. P 37.

¹⁸ Linda Bauld, Kathryn Angus and Marisa de Andrade “E-cigarette uptake and marketing”, *Public Health England* (2014) p.6.

¹⁹ Ibid; p.8

²⁰ Ibid; p.39.

Issue: There is a perceived risk that e-cigarettes may perpetuate the habit of tobacco cigarette use in existing smokers by continuing addiction to nicotine and the psychosocial behaviours associated with smoking

Evidence: Nicotine replacement therapy (NRT) products are already widely accepted as an appropriate smoking cessation tool subjected to rigorous efficacy and safety assessment. These products do not discontinue a smoker's addiction to nicotine, but reduce harm by offering a safe delivery method. Whilst all of the risks associated with e-cigarettes are still unknown, the Foundation would argue that there is no clear rationale for restricting or prohibiting their use on the basis that they contain nicotine and continue nicotine addiction.

It has also been argued that e-cigarettes may reduce the imperative some feel to quit smoking, leading to long-term use, or co-use, with tobacco. As discussed above, evidence to date has found that e-cigarette use is higher among people who already smoke tobacco, suggesting that there is a trend of co-use. However, it does not follow that co-use increases or entrenches harmful conventional smoking. Conversely, current evidence suggests that e-cigarettes help smokers cut down the number of cigarettes they smoke.²¹ Replicating the behavioural component of smoking, as well as the nicotine content, may make e-cigarettes more effective than other NRT products for aiding smoking cessation. Sensory stimulation and simulation of smoking behaviour are important determinants of a product's effectiveness in reducing or ceasing smoking.^{22, 23} This is supported by the Cochrane Report which found that e-cigarettes were more successful than nicotine patches at reducing smokers' cigarette consumption.²⁴

The Foundation also notes that e-cigarettes without nicotine are already freely available in New Zealand. These products replicate smoking behaviour in the same way as nicotine containing e-cigarettes.

Issue: There is currently a lack of product consistency

Evidence: The limited testing that has been undertaken internationally has revealed wide variations in the toxicity of contents and emissions from the various products in the market. There is also a wide variance in the nicotine levels of different e-cigarettes, and between actual content and their disclosed ingredients. A United States study has found that nicotine levels of e-cigarettes were between 85-121% of what was labelled.²⁵ These variant levels were not likely to cause measurable harm to users, although product labelling and consistency is important in enabling users to make informed decisions. Regulation should account for these product differentials and should require that product contents are clearly communicated to consumers.

²¹ "E-cigarettes and their potential contribution to achieving the Smokefree 2012 goal" *Prepared for the National Smokefree Working Group* (August 2016).

²² J. Rose and E. Levin, "Inter relationships between conditioned and primary reinforcement in the maintenance of cigarette smoking" *Br J Addict* (1991) 86, 605-609. Hajek et al. 1989

²³ P. Hajek, M. Jarvis, M. Belcher, G. Sutherland, C. Feyerabend "Effect of smoke free cigarettes on 24hr cigarette withdrawal: a double-blind placebo-controlled study", *Psychopharmacology (Berl)* (1989): 97. P. 99-102.

²⁴ McRobbie et al. *Electronic cigarettes for smoking cessation and reduction (Review)* p.16.

²⁵ J. Etter, E. Zather and S. Svensson "Analysis of refill liquids for electronic cigarettes", *Addiction* (2013): 108.pp. 1671-1679.

Issue: Limited research into e-cigarettes and competing perspectives of their use has the potential to confuse health messaging to the public

Evidence: As discussed above there is consensus that e-cigarettes provide a safer alternative to tobacco smoking and that they may be a valuable tool in reducing harm caused by smoking. However, there is a risk of inconsistent messaging on the use of e-cigarettes, given the unknown risks as well as diverse perspectives on the issue. Whilst tobacco smoking is declining, rates remain higher among Maori and Pacific people, as well as young adults and socioeconomically disadvantaged populations²⁶. The risk and recommendations associated with the use of e-cigarettes needs to be effectively communicated, particularly to groups which bear the disproportionate burden of smoking-related illness and death. As with the regulation itself, public health messaging needs to be sensitive to the uncertainty surrounding e-cigarettes.

Creating more consistent and coherent regulation around e-cigarettes, as supported by the Ministry of Health's proposed changes, is a positive step towards constructive public health messaging.

Response to Ministry of Health's Policy Options

Q1: Do you agree that the sale and supply of nicotine e-cigarettes and nicotine liquids should be allowed on the local market, with appropriate controls?

The Foundation supports the Ministry's proposal to make all e-cigarettes (with and without nicotine) available for lawful sale and supply in New Zealand, subject to controls.

Q2: Are there other (existing or potential) nicotine delivery products that should be included in these controls at the same time? If so, what are they?

This submission is concerned with e-cigarettes and we will not be including comment on other nicotine delivery products.

Q3: Do you think it is important for legislation to prohibit the sale and supply of e-cigarettes to young people under eighteen years of age in the same way as it prohibits the sale and supply of smoked tobacco products to young people?

We agree that the prohibition of the sale and supply of e-cigarettes to children and young people under the age of 18 is a proportionate response to the unknown risks associated with e-cigarettes. As the product contains nicotine, an addictive chemical, we similarly feel that decisions on use should be made by adults.

Q4: Do you think it is important for legislation to control advertising of e-cigarettes in the same way it controls advertising of smoked tobacco products?

E-cigarettes are a potentially lifesaving product for many smokers, although there are some unknown and known risks associated with vaping. Advertising of e-cigarettes could be a valuable tool for reducing the harm caused by tobacco smoking if it is targeted appropriately, however, such targeting to avoid unintended promotional effects (e.g. with

²⁶ New Zealand Health Survey 2012-13.

young people and never smokers) is problematic – as evidenced by decades of persuasive advertising of tobacco and alcohol. Uncertainty around the issue of advertising warrants further consideration and we recommend that at this time advertising remain prohibited. As further research is undertaken on e-cigarettes, there may be greater justification for advertising to be permitted. Further analysis could be done on options in this regard. Accordingly, we recommend that the SFEA (or preferably our recommended stand-alone Act) provide for a similar definition for promotion, advertising and sponsorship of e-cigarettes to that provided for tobacco products in the SFEA, prohibiting that advertising for now, except as provided by (future) regulations.

We support restriction on advertising health claims to only those products approved by Medsafe as smoking cessation aids.

Q5: Do you think it is important for the SFEA to prohibit vaping in designated smoke-free areas in the same way as it prohibits smoking in such areas?

The second-hand impact of vaping is still not clear, and the use of e-cigarettes in public places can be intrusive. However, as identified in the recent National Smokefree Working Group background paper *E-cigarettes and their potential contribution to achieving the Smokefree 2025 goal*, regulation of e-cigarettes should not be more stringent than that of smoked tobacco cigarettes²⁷. In the interests of consistency with existing tobacco smoking legislation, ease of compliance and the unknown harm of second-hand vaping, we recommend that e-cigarette use be prohibited in the same areas designated as ‘smokefree’ under the SFEA.

Q6: Do you agree that other controls in the SFEA for smoked tobacco products should apply to E-cigarettes?

The Foundation agrees that some controls referenced in the consultation document are appropriate for e-cigarette regulation. Nicotine has a psychoactive effect and can be lethal in very large quantities²⁸. We therefore support the regulation of some e-cigarette ingredients, such as maximum nicotine dosage. While we can see the argument that the addition of certain flavourings may increase the appeal of vaping to children, we are not convinced that the case has yet been proven that there should be regulation in this area or what specific ingredients should be limited or banned. There is reference in the consultation document to a few flavours but there may be many other alternative flavours that would simply replace these if they were banned. We therefore support further research and policy work on this and would welcome more detailed proposals. Regulation-making powers should be provided in the primary legislation so that regulations could be made in the future once the policy work has been undertaken.

In support of safe dosage regulations, we support a testing regime to confirm product safety and content purity, including the requirement for annual testing and disclose of product content.

²⁷ *E-cigarettes and their potential contribution to achieving the Smokefree 2012 goal*. National Smokefree Working Group. p. 3

²⁸ B. Mayer “How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the 19th century” *Arch Toxicol* (2014): 88, no.1. pp. 5-7. *The medium lethal does is estimated to be between 6.5 and 13mg/kg.*

However, we do not support the requirement for graphic health warnings. Given the potentially significant role for e-cigarettes in reducing harm to smokers' health, requiring graphic health warnings for e-cigarettes poses the significant risk of creating confusing messages to users and potential users. Not smoking at all is likely to be the best option for users' health, but using e-cigarettes is strongly preferable to smoking. Graphic warnings can powerfully communicate a simple message, such as the unequivocally negative health effects of tobacco smoking. Such messaging is not appropriate for e-cigarettes which may play a lifesaving role for some smokers. The health risks associated with e-cigarettes are still unknown. Associating health conditions with e-cigarettes before such links have actually been established is misleading and may undermine the credibility of public health messaging around smoked tobacco products.

The Foundation does not have a position on the prohibition on displaying products in sales outlets, restricting the use of vending machines, the requirement to provide annual returns on sales data, free distribution and awards associated with sales/discounting, or requirements for standardised packaging.

Q7 Do you think it is important for legislation to impose some form of excise or excise-equivalent duty on nicotine e-liquid, such as it does on tobacco products?

The Foundation believes that e-cigarette regulation should support a move towards e-cigarettes as a safer alternative to tobacco cigarettes. Taxing e-cigarettes is inconsistent with this approach and we do not support it.

Q8 Do you think quality control of and safety standards for e cigarettes are needed?

As with any new consumer product being brought to the market, we agree that some quality control and safety standardisation is needed. In particular, we support the need for childproof containers, good manufacturing practice and product consistency, including product labelling. We are ambivalent on registration/licensing of either manufacturers or sellers, or of products, and would like to see more detailed analysis of these options.

Further comments

We note the continuation of current limitations to the marketing of e-cigarettes as a smoking cessation tool, which requires Medsafe approval under the Medicines Act 1981. The existing evidence base indicates the effectiveness of e-cigarettes as a smoking cessation tool, and supports their potential to significantly reduce death and disability caused by smoking. Noting that this potential is the basis for the proposals in the consultation document to legalise nicotine containing e-cigarettes and the importance of consistent and clear messaging to users and potential users, we recommend that Medsafe develop a favourable approach towards the approval and marketing of e-cigarettes as a smoking cessation tool, subject to safe product requirements and the usual assessment around claims of efficacy.

Please contact me if you require any further information or clarification on our submission.

Yours sincerely

Ross Bell
Executive Director

About the Drug Foundation

The New Zealand Drug Foundation was established in 1989. It is an independent trust with a national focus on minimising drug—related harm. This includes social and health harms caused by legal drugs, such as tobacco and alcohol, as well as illegal drugs, such as cannabis.

The Drug Foundation advocates evidence—based policy on these issues, and provides reliable and credible information to organisations and individuals. We take a lead role in networking and cooperation within the alcohol and drug sector.

The Drug Foundation recognises that drugs, legal and illegal, are a part of everyday life experience. Drugs, and their use, impact on many of us, and on the people we care about. Harms to individuals and families include injury, disease, social, personal and financial problems and a reduced quality of life. Harms to society include unsafe communities, increased need for law enforcement, and high health and economic costs. For these reasons, the Drug Foundation is committed to reducing drug use and its harmful consequences.

This commitment to reducing harm includes ensuring that any illicit drugs, if used, are used safely. Our focus is on advocating for policies that build a healthy society where there is the least possible harm from drug use. All efforts to control or reduce the harm from drugs must be evidence based, socially just and maintain the rights of individuals and the aspirations of communities.

The Drug Foundation provides leadership and representation for our nationwide membership of organisations and individuals working on alcohol and drug issues. The Drug Foundation is a member of the International Harm Reduction Association, the Global Alcohol Policy Alliance, the Vienna NGO Committee on Narcotic Drugs and the International Drug Policy Consortium.

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