

# Appendix A: Product safety requirements

Proposed New Zealand requirements	How New Zealand requirements relate to European Union (EU) and United Kingdom legislation and guidance <sup>1,2,3</sup>
<b>Substances</b>	
<b>Manufacturing</b>	
1. Manufacturing involving the use of hazardous substances is subject to the Health and Safety at Work Act 2015 (and regulations and orders made under that Act), and products containing hazardous substances may also need approval under the Hazardous Substances and New Organisms Act 1996.	This is a reminder of requirements under other legislation specific to New Zealand relating to health and safety at work.
2. Only people who have been trained to handle nicotine safely are permitted to perform the commercial manufacture of vaping substances containing nicotine.	This is a reminder of requirements under other legislation specific to New Zealand relating to health and safety at work.
3. People must use appropriate personal protective equipment when handling nicotine.	This is a reminder of requirements under other legislation specific to New Zealand relating to health and safety at work.
4. An importer or manufacturer of vaping substances must have a system in place for: <ul style="list-style-type: none"> <li>(a) investigating and resolving complaints about vaping substances they are marketing</li> <li>(b) recording and notifying the Ministry of Health of any adverse reactions to vaping substances</li> <li>(c) recalling vaping substances from sale, supply or distribution</li> <li>(d) informing the Ministry of Health of:               <ul style="list-style-type: none"> <li>(i) the extent of a recall and its outcome</li> </ul> </li> </ul>	Matches the intent of the UK legislation.

<sup>1</sup> <https://www.legislation.gov.uk/ukxi/2016/507/part/6/made>

<sup>2</sup> <https://www.gov.uk/guidance/e-cigarettes-regulations-for-consumer-products>

<sup>3</sup> Standard PAS 54115:2015.

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(ii) any risks or concerns that may arise about any substances used in the manufacture of vaping substances.	
<b>Labelling</b>	
<p>5. The label of vaping substance containers must include the following information:</p> <ul style="list-style-type: none"> <li>(a) safety of use instructions (including storage, refilling, recharging and disposal)</li> <li>(b) names and quantities (in mg) of the substance's ingredients</li> <li>(c) volume or weight of substance in the container (in mL or mg as appropriate)</li> <li>(d) manufacturing batch number</li> <li>(e) manufacturer's name and contact details</li> <li>(f) expiry date (as M/YY, MM/YY, M/YYYY or MM/YYYY)</li> <li>(g) for vaping substances, the ratio of propylene glycol to vegetable glycerine (expressed as PG:VG or as a percentage), or the amount or proportion of carrier oil(s) present</li> <li>(h) for substances containing more than 3% alcohol, the words 'contains alcohol'</li> <li>(i) for substances containing nicotine, nicotine concentration (in mg/mL)</li> <li>(j) for substances not containing nicotine, the words 'non-nicotine' or 'zero nicotine'.</li> </ul>	
<b>Ingredients</b>	
6. Notifiable products must only contain the ingredients that the notifier submits in the product notification, in the amounts included in that notification, other than trace levels that are technically unavoidable during manufacture.	Aligns with UK legislation.
7. Where a notifiable product contains additives other than flavourings, such as preservatives or antioxidants, the notifier must include a justification for their use and a toxicological risk assessment with the product notification.	Aligns with UK legislation.
8. Notifiable products must not contain ingredients that pose an unacceptable risk to people's safety in heated or unheated form.	Aligns with UK legislation.

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<p>Note: The absence of an ingredient from the list of prohibited substances in requirement 15 does not mean that it is safe for use in notifiable products. The notifier must make their own assessment of the safety of each ingredient in their product and the controls needed to ensure their product does not pose an unacceptable risk.</p>	
<b>Quality of ingredients</b>	
9. Nicotine quality must comply with the United States (USP) or European Pharmacopoeia (Ph Eur) monograph.	Aligns with UK guidance.
10. Propylene glycol, glycerine (vegetable glycerol) and the acid of the nicotine salt quality must comply with the USP or Ph Eur monograph.	Aligns with UK guidance.
11. Alcohol (ethanol) quality must comply with the USP monograph for Alcohol or Alcohol 96%, or the Ph Eur monograph for Ethanol or Ethanol 96%.	Aligns with UK guidance.
12. Purified water quality must comply with the USP or Ph Eur monograph.	Aligns with UK guidance.
13. Tobacco extracts used for flavourings must not contain tobacco-specific nitrosamines above concentrations shown in requirement 34.	Aligns with UK guidance and adds a limit for allowable trace levels.
<p>14. Flavourings must be water-soluble, and flavourings other than tobacco extracts must meet food grade standards.</p> <p>Flavouring substances are considered to be food grade if they comply with the specifications in <a href="#">Schedule 3</a> of the Australia New Zealand Food Standards Code or a Food Chemicals Codex monograph.</p>	The UK legislation does not have this requirement. We propose prohibiting oil- and fat-based ingredients in vaping liquids due to concern about the risk of lipoid pneumonia.
<b>Prohibited substances</b>	
<p>15. Notifiable products must not contain the following substances (including in flavourings), unless present in trace levels that are technically unavoidable during manufacture.</p> <p>Any such trace levels must not exceed the maximum levels set in requirement 34. If requirement 34 does not set a limit for a particular substance, trace levels of that substance are not permitted.</p> <p>(a) carcinogenic, mutagenic, reprotoxic substances (CMRs)</p>	Aligns with the UK legislation by setting a prohibited substances list, rather than a more restrictive permitted substances list.

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<ul style="list-style-type: none"> <li>(b) specific target organ toxicity (STOT-RE) Category 1 substances</li> <li>(c) respiratory sensitisers</li> <li>(d) radioactive substances</li> <li>(e) colouring substances</li> <li>(f) any pharmacologically active substance (medicinal, psychoactive, narcotic, anabolic or herbal) other than nicotine</li> <li>(g) vegetable oils other than glycerine</li> <li>(h) mineral oils</li> <li>(i) caffeine</li> <li>(j) taurine</li> <li>(k) glucuronolactone</li> <li>(l) ethylene glycol</li> <li>(m) diethylene glycol</li> <li>(n) polyethylene glycol</li> <li>(o) food or dietary supplements, including vitamins</li> <li>(p) probiotics</li> <li>(q) formaldehyde releasers, including: <ul style="list-style-type: none"> <li>(i) quaternium-15</li> <li>(ii) imidazolidinyl urea</li> <li>(iii) diazolidinyl urea</li> <li>(iv) 2-bromo-2-nitropropane-1,3-diol (or 2-bromo-2-nitro-1,3-propanediol)</li> <li>(v) dimethyl-dimethyl hydantoin (DMDM hydantoin)</li> <li>(vi) (benzyloxy)methanol (or phenylmethoxymethanol)</li> <li>(vii) 2-choloro-N-(hydroxymethyl)acetamide</li> <li>(viii) hexahyro-1,3,5-tris(hydroxyethyl)-s-triazine</li> </ul> </li> </ul>	<p>To align with the UK legislation and extend beyond it to include other substances, the list has been drafted using:</p> <ul style="list-style-type: none"> <li>• the list of flavouring ingredients considered by the Flavor and Extract Manufacturers Association to present a high risk to respiratory injury</li> <li>• substances not allowed in vaping liquids in the voluntary standards for e-cigarettes by the <ul style="list-style-type: none"> <li>– American E-Liquid Manufacturing Standards Association</li> <li>– British Standards Institute</li> <li>– Association Française de Normalisation</li> </ul> </li> <li>• ingredients prohibited in the Canadian Tobacco and Vaping Products Act.</li> </ul> <p>This list will be extended as and when further substances are identified but notifiers must comply with requirement 8 and make their own assessment of the safety of each ingredient in their product, and the controls needed to ensure their product does not pose an unacceptable risk.</p>

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<ul style="list-style-type: none"> <li>(ix) sodium hydroxymethyl glycinate</li> <li>(r) sugars and sweeteners, including:               <ul style="list-style-type: none"> <li>(i) glucose</li> <li>(ii) sucrose</li> <li>(iii) fructose</li> <li>(iv) lactose</li> <li>(v) maltose</li> <li>(vi) saccharose</li> <li>(vii) acesulfame potassium</li> <li>(viii) aspartame</li> <li>(ix) sodium saccharinate</li> <li>(x) stevia</li> </ul> </li> <li>(s) the following preservatives:               <ul style="list-style-type: none"> <li>(i) triclosan</li> <li>(ii) phenoxyethanol</li> <li>(iii) isothiazolinone</li> <li>(iv) long-chain parabens, including isopropylparaben and its salts, isobutylparaben, phenylparaben, benzylparaben and pentylparaben.</li> </ul> </li> </ul>	
Nicotine strength	
16. The strength of free-base nicotine in vaping substances must not exceed 20 mg/mL.	Aligns with UK legislation.
17. The strength of nicotine salt in vaping substances must not exceed 50 mg/mL.	The UK legislation does not set a limit specific to nicotine salts. The UK limit of 20 mg/mL of nicotine in nicotine-containing liquid sold for retail applies to nicotine salts

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	<p>as well. Nicotine salts are less alkaline than free-base nicotine, allowing higher concentrations that provide nicotine absorption levels closer to those from smoking cigarettes. Nicotine salts may be an effective alternative for long-term smokers. There is no current evidence that products containing nicotine salts are any more harmful than those with free-base nicotine.</p>
<p>18. For vaping substances sold at retail, the total nicotine content in a container must not exceed 500 mg, whether it is present as free-base nicotine or nicotine salts.</p>	<p>The UK legislation sets maximum limits on the size of containers as a means of limiting the amount of nicotine in any given container for vaping products sold by retail. There is a risk that someone, particularly a child, ingesting an entire container of nicotine vaping substance would suffer significant harm and potentially death. A 2014 study<sup>4</sup> found doses of 0.5–1.0 g of oral nicotine was the lower fatal limit for adults (corresponding to an oral LD<sub>50</sub> of 6.5–13 mg/kg). For New Zealand requirements, we propose placing a direct limit on the total nicotine in a container so a maximum limit is maintained but lower concentrations can still be sold in larger containers. This limit is designed to work in combination with</p>

<sup>4</sup> Mayer B. 2014. How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century. *Archives of Toxicology* 88(1): 5–7. URL: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3880486/> (accessed 10 November 2020).

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	requirements 21–23 to manage the risk of accidental ingestion of harmful levels of nicotine. We propose this limit based on the lower fatal limit for adults identified in the 2014 study.
Containers	
19. Plastics used for vaping substance containers must be of food grade.	Not covered under UK legislation but we consider this requirement to be beneficial for the New Zealand regulations.
20. Vaping substance containers must be protected against breakage and leakage.	Aligns with UK legislation.
21. All vaping substance containers must have child-resistant closures and tamper-evident measures unless the container is sealed and intended to be opened only within a vaping device.	Aligns with UK legislation.
22. Vaping substance containers sold at retail must not exceed 100 mL capacity unless the vaping substance contains zero nicotine.	The UK legislation sets a limit of 10 mL, which would be quite disruptive to the New Zealand market, where the majority of containers have a capacity of 30 mL or more. Our proposal is to manage risk by limiting the amount of nicotine in a container, so we propose a significantly higher limit on container capacity than the UK legislation.
23. Anti-spill or restricted flow inserts must be used and must comply with the EU Commission Implementing Decision (EU) 2016/586 <sup>5</sup> on technical standards for the refill mechanism of electronic cigarettes.	Aligns with the UK legislation.

<sup>5</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016D0586&from=EN>

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<b>Devices</b>	
24. Devices must be safe and fit for purpose under normal use and conditions, and comply with all relevant New Zealand legislation, including the Electricity (Safety) Regulations 2010.	Aligns with principle of the UK legislation.
25. Device batteries must conform to IEC 62133-1 or IEC 62133-2 of the International Electrotechnical Commission, as applicable.	Aligns with principle of the UK legislation.
26. Devices must have a mechanism to ensure user and battery safety in the event of a short-circuit of the heating element.	Aligns with principle of the UK legislation.
27. Rechargeable devices must have a mechanism to prevent the battery from being discharged below a safe voltage during use or being discharged faster than the battery can sustain safely.	Aligns with principle of the UK legislation.
28. Devices with an on-board charger must have circuitry to monitor the battery voltage and charging current, and limit these to safe levels. Where multiple battery cells are in series, the cells must be monitored individually.	Aligns with principle of the UK legislation.
29. A device must be able to deliver a dose of nicotine at consistent levels under normal conditions of use.	Aligns with UK legislation.
30. Devices must have a serial or batch number that allows the device to be traced to the time and place of its manufacture. Single-use devices may have the serial or batch number on their package instead of on the device.	Aligns with UK legislation.
31. If the wick in a device is silica-based, emissions must be examined to ensure that needles or other dangerous small particles are not being generated. If needles or other dangerous small particles are identified in emissions, the wicking material grade must be changed.	Aligns with UK legislation.
<b>Vaping substance testing</b>	
32. Notifiers must ensure that testing is carried out by a laboratory that has demonstrated technical competence through accreditation to ISO/IEC 17025 (eg, International Accreditation New Zealand	The UK legislation is highly prescriptive in its requirements for testing of products, which include specifying consistency levels

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(IANZ), ANSI National Accreditation Board (ANAB) or National Association of Testing Authorities (NATA) accreditation), and that testing methods are fit for purpose and are validated.	<p>of nicotine delivery, and how to undertake testing for both devices and liquids. This information is then to be reported back to the Department of Health.</p> <p>Our proposal for the New Zealand regulations is less prescriptive about how to conduct testing because testing methods will change and improve over time. We do not propose requiring test results to be submitted to the Ministry of Health unless requested.</p>																
33. For vaping substances that have a shelf life set at longer than two years, testing must include a stability programme to monitor the product over its shelf life.	Not covered under UK legislation but we consider this requirement is necessary to reduce the risk of harmful breakdown products being present in vaping substances with longer shelf lives.																
34. Substances present in trace levels in notifiable products, where such trace levels are technically unavoidable during manufacture, must not exceed the limits specified for the following contaminants.	Aligns with the UK legislation and expands on it to include limits on contaminants that it may not be possible to exclude completely from notifiable products.																
<table border="1"> <thead> <tr> <th data-bbox="280 1102 770 1158">Compounds</th> <th colspan="3" data-bbox="770 1102 1413 1158">Limit value (no more than)</th> </tr> </thead> <tbody> <tr> <td data-bbox="280 1158 770 1214">Diacyetyl (or 2,3-butane dione)</td> <td data-bbox="770 1158 965 1214">22 mg/L</td> <td data-bbox="965 1158 1160 1214">22 ppm</td> <td data-bbox="1160 1158 1413 1214">0.0022%</td> </tr> <tr> <td data-bbox="280 1214 770 1310">Pentane 2,3-dione (or acetylpropionyl)</td> <td data-bbox="770 1214 965 1310">22 mg/L</td> <td data-bbox="965 1214 1160 1310">22 ppm</td> <td data-bbox="1160 1214 1413 1310">0.0022%</td> </tr> <tr> <td data-bbox="280 1310 770 1359">Formaldehyde</td> <td data-bbox="770 1310 965 1359">22 mg/L</td> <td data-bbox="965 1310 1160 1359">22 ppm</td> <td data-bbox="1160 1310 1413 1359">0.0022%</td> </tr> </tbody> </table>	Compounds	Limit value (no more than)			Diacyetyl (or 2,3-butane dione)	22 mg/L	22 ppm	0.0022%	Pentane 2,3-dione (or acetylpropionyl)	22 mg/L	22 ppm	0.0022%	Formaldehyde	22 mg/L	22 ppm	0.0022%	<p>Proposed limit values for compounds and metals have come from the UK guidance.</p> <p>Proposed limit values for metals have come from ICH Q3D<sup>6</sup> using a daily usage of 5 g per day. Where no limit values were available in ICH, we extrapolated values based on similar inhalation concerns or</p>
Compounds	Limit value (no more than)																
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<sup>6</sup> European Medicines Agency. ICH Q3D Elemental purities. URL: <https://www.ema.europa.eu/en/ich-q3d-elemental-impurities> (accessed 10 November 2020).

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Acrolein	22 mg/L	22 ppm	0.0022%	<p>from calculations based on international guidance.</p> <p>The tobacco-specific nitrosamines (TSNAs) limit recognises that low levels of TSNAs may be unavoidable in products derived from tobacco. It is based on chapter 5, 'Toxicology of e-cigarette constituents',<sup>7</sup> of the 2018 report <i>Public Health Consequences of E-Cigarettes</i>.</p>
Acetaldehyde	200 mg/L	200 ppm	0.02%	
Ethylene glycol	1,000 mg/L	1,000 ppm	0.1%	
Diethylene glycol	1,000 mg/L	1,000 ppm	0.1%	
<b>Metals</b>	<b>Limit value (no more than)</b>			
Aluminium	12 mg/L	12 ppm	0.0012%	
Antimony	4 mg/L	4 ppm	0.0004%	
Arsenic	0.4 mg/L	0.4 ppm	0.00004%	
Cadmium	0.6 mg/L	0.6 ppm	0.00006%	
Chromium	0.6 mg/L	0.6 ppm	0.00006%	
Iron	12 mg/L	12 ppm	0.0012%	
Lead	1 mg/L	1 ppm	0.0001%	
Mercury	0.2 mg/L	0.2 ppm	0.00002%	
Nickel	1 mg/L	1 ppm	0.0001%	
Tin	12 mg/L	12 ppm	0.0012%	
<b>Tobacco-specific nitrosamines</b>	<b>Limit value (no more than)</b>			
Total TSNAs, including: <ul style="list-style-type: none"> <li>• N-nitrosornicotine</li> <li>• N-nitrosoanatabine</li> </ul>	50 µg/L	0.05 ppm	0.000005%	

<sup>7</sup> Stratton K, Kwan L, Eaton D (eds). 2018. Toxicology of e-cigarette constituents. In *Public Health Consequences of E-Cigarettes*. Washington, DC: National Academies Press. URL: <https://www.ncbi.nlm.nih.gov/books/NBK507184/> (accessed 10 November 2020).

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	<ul style="list-style-type: none"> <li>• N-nitrosoanabasine</li> <li>• 4-methyl-N-nitrosamino-1-(3-pyridyl)-1-butanone</li> </ul>				