

UK DISCUSSION PAPER ON SUBMISSION OF NOTIFICATIONS
UNDER ARTICLE 20 OF DIRECTIVE 2014/40/EU

CHAPTER 6 – ADVICE ON INGREDIENTS IN NICOTINE-CONTAINING
LIQUIDS IN ELECTRONIC CIGARETTES AND REFILL CONTAINERS

INTRODUCTION

Article 20(2) of Directive 2014/40/EU [TPD] places an obligation on the manufacturers and importers of electronic cigarettes to submit a notification to the competent authorities of the Member States of such products they intend to market.

Article 20(2)(b) and (c) of the TPD requires the notification to include a list of all ingredients in the product and toxicological data regarding the product's ingredients and emissions.

The European Commission has established a common format for the notification of these products within [Commission Implementing Decision \(EU\) 2015/2183](#) of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers. The submission format is set out in the annex to that Decision and the information required on ingredients is set out in section 4 of the annex.

Article 20(3) of the TPD places a requirement on member states to ensure that nicotine-containing liquid in electronic cigarettes and refill containers does not contain additives listed article 7(6) of the TPD and, except for nicotine, only includes ingredients that do not pose a risk to human health in heated or unheated form.

Article 7(6) states the following:

Member States shall prohibit the placing on the market of tobacco products containing the following additives:

- (a) vitamins or other additives that create the impression that a tobacco product has a health benefit or presents reduced health risks;
- (b) caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality;
- (c) additives having colouring properties for emissions;
- (d) [for tobacco products for smoking, additives that facilitate inhalation or nicotine uptake;] and
- (e) additives that have CMR¹ properties in unburnt form.

WHAT IS REQUIRED

The TPD requires information about each ingredient in notifiable products to be included within the submission. The information should include identifying details, the quantity and function of the ingredient and further information about its classification and various aspects of its toxicity. Details of all available toxicological studies on the ingredient in unheated and heated form and emissions should be submitted.

¹ CMR = carcinogenic, mutagenic or reprotoxic.

The notifier should consider carefully the implications for their product of the toxicological data for the safety of each ingredient and its associated emissions as part of their responsibilities under the TPD and general consumer safety legislation to ensure that products supplied to consumers are safe². Submitters must include in their notification a declaration that they bear full responsibility for the quality and safety of the product when placed on the market and used under normal or reasonably foreseeable conditions.

A list of substances that should not be included as ingredients in electronic cigarettes and refill containers is set out below. This list is not exhaustive and may be added to in future as more information becomes available. For the avoidance of doubt, the fact that an ingredient does not appear in this list does not mean that it is safe for use in e-liquids. The notifier should make their own assessment of the safety of each ingredient in their product and the need to control for levels of substances such as formaldehyde that are not present as an ingredient.

SUBSTANCES NOT PERMITTED AS INGREDIENTS IN E-LIQUIDS

From the TPD:

- any ingredient that poses a risk to human health in heated or unheated form
- vitamins or other additives that create the impression that a tobacco product has a health benefit or presents reduced health risks;
- caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality;
- additives having colouring properties for emissions;
- additives that have carcinogenic, mutagenic or reprotoxic (CMR) properties in unburnt form.

From national standards:

- Substances classified as carcinogenic, mutagenic or reprotoxic (CMR categories³ 1 and 2)
- Substances classified with specific target organ toxicity for the respiratory tract (STOT category³ 1)
- Respiratory sensitizers
- Vitamins used as food supplements
- Stimulant additives such as caffeine or taurine
- Diacetyl
- Pentane 2,3 dione
- Diethylene glycol
- Ethylene glycol
- Formaldehyde*
- Acetaldehyde*
- Acrolein*
- Metals, including cadmium, chromium, iron, lead, mercury and nickel
- Preservatives liable to release formaldehyde.

*See also requirements for testing these substances in the emissions guidance.

² See <https://www.gov.uk/guidance/product-liability-and-safety-law>

³ Definitions of these terms and listings of hazardous substances can be found in Regulation (EC) No. 1272/2008 (as amended) on classification, labelling and packaging of substances and mixtures at <http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A02008R1272-20150601>.

FLAVOURINGS

[Commission Implementing Decision \(EU\) 2015/2183](#) states that ingredients present at a level below 0.1% of the final product formulation may be deemed confidential or a trade secret. Below that level, MHRA will allow ingredients to be considered as confidential in the notification. As such, ingredients present at a level below 0.1% of the final formulation can now be described collectively in the notification by an umbrella term such as ‘strawberry flavouring’.

In these cases, the notifier must gain the following from the ingredient supplier:

- (i) adequate assurance of quality and safety to allow the notifier to accept full responsibility for the product under Article 20(2)(g) of the TPD and
- (ii) an assurance that the ingredient supplier would disclose the composition to the competent authority (MHRA in the UK) in confidence the event of a safety problem with the product.

Notifiers must satisfy themselves as to the safety and quality of their product but may wish to seek assurances that:

- a) the ingredient complies with applicable EU food flavouring legislation ([Regulation EC 1334/2008](#)).
- b) the flavouring substances contained within the flavour are listed in the EU list of flavouring substances as defined by [Regulation EU 872/2012](#).
- c) The ingredient formulation does not include any substance banned under Article 7 of the TPD.

The notifier and flavour supplier should in particular consider the safety of the flavour ingredients when used in an e-cigarette. See also the advice above about toxicological studies. Where details of ingredients present at levels below 0.1% are not submitted with the notification, toxicological data on each ingredient must be provided if requested by the competent authority in the event of a safety problem with the product.