

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

CHAPTER 5 – ADVICE ON NAMES AND PRESENTATION OF  
NICOTINE-CONTAINING ELECTRONIC CIGARETTES AND REFILL  
CONTAINERS ON PACKAGING

**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(4)(b) of the TPD places a requirement on member states to ensure that unit packets and any outside packaging of electronic cigarettes and refill containers does not include elements or features referred to in article 13(1) of the TPD, except for information on nicotine content and flavourings.

Article 13 states the following:

1. The labelling of unit packets and any outside packaging and the tobacco product itself shall not include any element or feature that:
  - (a) promotes a tobacco product or encourages its consumption by creating an erroneous impression about its characteristics, health effects, risks or emissions; labels shall not include any information about the nicotine, tar or carbon monoxide content of the tobacco product;
  - (b) suggests that a particular tobacco product is less harmful than others or aims to reduce the effect of some harmful components of smoke or has vitalising, energetic, healing, rejuvenating, natural, organic properties or has other health or lifestyle benefits;
  - (c) refers to taste, smell, any flavourings or other additives or the absence thereof;
  - (d) resembles a food or a cosmetic product;
  - (e) suggests that a certain tobacco product has improved biodegradability or other environmental advantages.
2. The unit packets and any outside packaging shall not suggest economic advantages by including printed vouchers, offering discounts, free distribution, two-for-one or other similar offers.
3. The elements and features that are prohibited pursuant to paragraphs 1 and 2 may include but are not limited to texts, symbols, names, trademarks, figurative or other signs.

Information on the intention of these provisions is provided in TPD recital 27 which states:

“Tobacco products or their packaging could mislead consumers, in particular young people, where they suggest that these products are less harmful. This is, for example, the case if certain words or features are used, such as the words ‘low-tar’, ‘light’, ‘ultra-light’, ‘mild’, ‘natural’, ‘organic’, ‘without additives’, ‘without flavours’ or ‘slim’, or certain names, pictures, and figurative or other signs. Other misleading

elements might include, but are not limited to, inserts or other additional material such as adhesive labels, stickers, onserts, scratch-offs and sleeves or relate to the shape of the tobacco product itself. Certain packaging and tobacco products could also mislead consumers by suggesting benefits in terms of weight loss, sex appeal, social status, social life or qualities such as femininity, masculinity or elegance. Likewise, the size and appearance of individual cigarettes could mislead consumers by creating the impression that they are less harmful. Neither the unit packets of tobacco products nor their outside packaging should include printed vouchers, discount offers, reference to free distribution, two-for-one or other similar offers that could suggest economic advantages to consumers thereby inciting them to buy those tobacco products.”

## **WHAT IS REQUIRED**

This guidance sets out MHRA’s interpretation of article 13 of the TPD as it applies to electronic cigarettes and refill containers. We understand that the reasons for these restrictions are to ensure that people are not misled as to the nature of the product or its effects on health or invited to choose a particular option because of a perceived comparative benefit against other e-cigarette products that may be erroneous.

Advice is given on specific aspects below. This should not be seen as a complete statement of TPD requirements and we have not made a comment where the interpretation appears to be obvious.

*“1. The labelling of unit packets and any outside packaging for electronic cigarettes and refill containers and the product itself shall not include any element or feature that:*

*(a) promotes the product or encourages its consumption by creating an erroneous impression about its characteristics, health effects, risks or emissions;”*

We interpret this as including a prohibition on misleading safety claims, such as that the product is ‘safe’ or ‘risk-free’. It would also preclude claims for any health benefits of using the product. Any representation of a food ingredient, such as a picture of fruit on the pack, would only be permitted if the product contains that ingredient or flavouring. Any reference to food ingredients should not suggest the product is a ‘healthy’ option (see also point (d) below).

*“(b) suggests that a particular product is less harmful than others or aims to reduce the effect of some harmful components of smoke or has vitalising, energetic, healing, rejuvenating, natural, organic properties or has other health or lifestyle benefits;”*

We interpret this as including a prohibition on any comparative safety claims vs other e-cigarette products. It would also prohibit claims for benefits from using the product or from its ingredients including any suggestion of effects on energy or health (and related terms). Any description of an ingredient as of ‘natural’ origin or organically produced would be similarly prohibited. It would not prohibit an accurate statement of fact relating to the non-inclusion of particular components, ingredients or emissions of tobacco products.

In addition, we interpret these two provisions as preventing any characterisation of a product as ‘light’, ‘mild’ or similar terms. This would also include any such references in the name of the product.

It would also preclude any suggestion in the name or graphics that use of the product confers social status or sexual benefits.

*“(c) refers to taste, smell, or any additives other than flavourings or the absence thereof;”*

We interpret this as prohibiting any references to the smell or taste of the product, apart from references to flavour. It would not include a prohibition on an accurate statement of fact relating to the non-inclusion of particular tobacco components.

*“(d) resembles a food or a cosmetic product;”*

We interpret this as requiring that the presentation of the product does not mislead consumers as to the nature of the product. It should be clear that the product is not a food or cosmetic product.

References to foods or food ingredients are permissible in the name or on the pack as factual descriptions of a flavour ingredient of the product, provided the nature of the product is clear (see also point (a) above).

*“(e) suggests that a certain product has improved biodegradability or other environmental advantages.”*

We interpret this as including a prohibition on any reference to the product being eco-friendly, environmentally ‘green’ or similar as well as any comparative biodegradability or environmental claims versus other e-cigarette products. This would also include any such references in the name of the product.

*“2. The unit packets and any outside packaging shall not suggest economic advantages by including printed vouchers, offering discounts, free distribution, two-for-one or other similar offers.”*

*“3. The elements and features that are prohibited pursuant to paragraphs 1 and 2 may include but are not limited to texts, symbols, names, trademarks, figurative or other signs.”*

This is a wide description designed to include all elements of the product, its name and the design and content of its packaging and labelling. This would include words, pictures, graphics, shape and other elements.

## **APPLICATION**

It is the responsibility of the person making the notification and placing the product on the market to ensure that their product conforms to the requirements of the TPD.

MHRA will review each notification on receipt against a minimum set of requirements to protect public health. We will also review at any time any notifications if we receive information that a product may contravene the legal requirements set out in the TPD. If in our opinion, the individual product does not conform to the requirements of the TPD, we will write to the notifying company informing them that the product may only be sold until 19 May 2017. Any company that does not agree with this opinion will have the opportunity to make representations which MHRA will consider before coming to a final decision on the notification. Any further recourse would be a matter for the Courts.

**MHRA**  
**August 2016**

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