Regulation of the Minister for Health, Welfare and Sport, dated , , amending the Tobacco and Smoking Products Regulation in relation to the imposition of requirements on refill packs and nicotine-free refill packs, and the setting of limit values for nicotine in tobacco-free nicotine products

The Minister of Health, Welfare and Sport,

Having regard to Article 2(7) and (8) of the Tobacco and Smoking Products Act and Article 2.5 of the Tobacco and Smoking Products Decree;

Hereby decrees:

Article I

The Tobacco and Smoking Products Regulation is amended as follows:

After Article 2.12, three articles shall be inserted with the following text:

Article 2.13

1. A refill pack shall indicate the nicotine content of the product, expressed in milligrams per millilitre, and the nicotine release per dose. A nicotine-free refill pack shall bear a statement indicating that the product does not contain nicotine.
2. A refill pack or nicotine-free refill pack shall be marked with a list of all the ingredients of the product and the batch number.
3. Insofar as the recommendation to keep a product out of the reach of children is not mandatory under Regulation (EC) No 1272/2008, that recommendation shall be stated on refill packaging in addition to the requirements of that Regulation.
4. A refill pack or a nicotine-free refill pack must not bear any element or feature that:
   a. promotes the tobacco or encourages its consumption by creating an erroneous impression about its characteristics, health effects, risks or emissions;
   b. suggests that the product is less harmful than others or is aimed at reducing the effect of certain harmful components of vapour, or has activating, energetic, healing, rejuvenating, natural, biological properties or other positive effects on health or lifestyle;
   c. refers to a flavour, odour or additives, other than flavourings or aromas, or the absence thereof;
   d. resembles a food or cosmetic product;
   e. The suggestion implies that a particular product is more readily biodegradable or has other environmental benefits.
5. A refill pack or a nicotine-free refill pack shall not bear any indication of flavouring additives other than those specified in Article 2.12.

Article 2.14

1. The following warning must be displayed on a refill pack: ‘This product contains the very addictive substance nicotine. Its use is not recommended for non-smokers’.
2. The following warning must be displayed on a nicotine-free refill pack: ‘This product harms your health. Its use is not recommended for non-smokers’.
3. The warnings referred to in paragraphs 1 and 2:
   a. shall be positioned in such a way that they are fully visible and cannot be removed or obliterated;
   b. shall cover 30% of the surface area of the refill pack or nicotine-free refill pack;
   c. shall be displayed in black, bold typeface using the Helvetica font on a white background;
   d. shall be printed in a font size which ensures that the text occupies as large a proportion as possible of the surface reserved for the warning; and
   e. be centred on the surface area intended for them.
4. Without prejudice to Article 2.13, the part of the refill pack or nicotine-free refill pack not covered by the warning referred to in the first or second paragraph shall be transparent or the colour Pantone 448C with a matt and smooth finish. Article 3.10a(2) and (3), shall apply mutatis mutandis, on the understanding that the information referred to in Article 3.10a(2), may be affixed by means of a sticker, provided that this sticker cannot be removed.

Article 2.15
A nicotine product without tobacco contains:
a. where the nicotine product without tobacco contains only forms of nicotine other than 6-methylnicotine not exceeding 0.028 milligrams of nicotine per product unit; or
b. if the tobacco-free nicotine product contains 6-methylnicotine, the nicotine content must not exceed 0.0030 milligrams per unit of product, including 6-methylnicotine.

In Article 3.10(4), point (c), ‘odour’ is inserted after ‘flavour’.

C

A paragraph is inserted in Article 7.3 and reads:

4. A refill pack or nicotine-free refill pack that complies with the Tobacco and Smoking Products Regulation as it was in force on 31 December 2026 and that was produced or released for free circulation before 1 January 2027 may be placed on the market until 1 January 2028.

Article II

This regulation shall enter into force on 1 January 2027.

This Regulation and Explanatory Memorandum will be published in the Government Gazette.

The Minister for Public Health,
Welfare and Sports,

Explanation

I. General section

1. Introduction

Nicotine addiction is a serious form of addiction with very harmful health consequences. Nicotine addiction is often linked to smoking and smoking is the main avoidable cause of disease and death. Every half an hour a person dies from the consequences of smoking. The recent Coherent Effective Prevention Strategy (SEP) of the Ministry of Health, Welfare and Sport sets the objective of achieving a smoke-free generation by 2040.[1] This means that by 2040, no young people will be smoking and no more than 5% of adults will be smoking.

[1] Annex to Parliamentary Papers II 2024/25, 32793, No 846.

A smoke-free generation also means a nicotine-free generation, because not only the use of tobacco products is a danger to public health. The use of other products containing nicotine is also harmful. In order to reduce nicotine use, particularly among young people, the 'Action Plan against vaping' (hereinafter 'the Action Plan') was published in 2025.[2] The Action Plan addresses not only the prevention of the use of electronic vapour products (vaping) and tobacco products, especially among young people, but also the prevention of the use of nicotine products in general. In addition to electronic vapour products and tobacco products, the tobacco and nicotine industry also markets nicotine products without tobacco on the market. These are products that generally contain high levels of nicotine and come in tasty flavours that appeal to young people. These products do not fit in with the goal of a nicotine-free generation.

With effect from 1 January 2025, nicotine products without tobacco have been brought within the scope of the Tobacco and Smoking Products Act (hereinafter: the Act).[3] The possibility has been created by or pursuant to an order in council in the interest of public health to impose requirements on nicotine products without tobacco.[4] The Tobacco and Smoking Products Decree [Tabaks- en rookwarenbesluit, hereinafter: Decree] has been amended with effect from the same date so that requirements can be set by ministerial order with respect to the design and ingredients of nicotine products without tobacco.[5] The purpose of this amendment to the Tobacco and Smoking Products Regulation (hereinafter 'the Regulation') is to establish limit values for the nicotine content in nicotine products without tobacco. The explanatory memorandum to the amending decision on the regulation of nicotine products without tobacco and nicotine devices elaborated on the objectives, backgrounds and arguments for setting limit values for ingredients of nicotine products without tobacco.[6] The main elements of this measure will be briefly discussed below.

In addition, a ruling of the Trade Appeals Council [College van Beroep voor het bedrijfsleven] (hereinafter: (CBb) grounds for amending the scheme. The CBb considered that a vial in which refill liquid for electronic cigarettes is sold (a refill pack[7]) cannot be classified as the packaging (or more precisely the unit packet) of that product, but should be classified as the product ('the container') itself. It follows from the ruling that the applicable packaging requirements do not apply to refill packs.[8] That is an undesirable outcome for public health, because now, for example, no warnings are required on these refill packs. That is why this scheme also sets out requirements regarding the appearance of refill packs.

2. **Background**

Tobacco-free nicotine products
In recent years, the tobacco industry has expanded its portfolio and placed on the market several new products that do not contain tobacco but do contain nicotine. In 2020, the Netherlands' National Institute for Public Health and the Environment (RIVM) noted that two types of nicotine products without tobacco were available on the Dutch market at that time. These were, on the one hand, so-called 'steam stones' for use in a water pipe and, on the other hand, nicotine sachets.

Steam stones are nicotine-containing products intended for use in a hookah. Nicotine pouches are small, porous pouches containing a nicotine-based powder, which are placed under the (upper) lip so that the pouch releases nicotine into the bloodstream, thereby giving the user a 'kick'. Nicotine pouches fall under the legal definition of 'nicotine products without tobacco for oral use', which is more comprehensive than just nicotine pouches. The placing on the market of nicotine products without tobacco shall be prohibited.[9] The rules laid down in this Regulation therefore actually relate only to nicotine products without tobacco other than nicotine products without tobacco for oral use.

In addition to steam stones and nicotine pouches, the RIVM in its report expressed the expectation that other types of nicotine products without tobacco could also appear on the Dutch market in the years after the report was published. It is true that other nicotine products without tobacco have

[2] Annex to Parliamentary papers II 2024/25, 32011, no 119.

[3] Bulletin of Acts and Decrees 2024, 292.

[4] Article 2(8) of the Act.

[5] Article 2.5 of the Decree.

[6] Bulletin of Acts and Decrees 2024, 378.

[7] In accordance with Article 1 of the Act, the term 'refill pack' refers to refill packs containing a nicotine-containing liquid; for the sake of clarity, the term 'refill pack' is generally used in this explanatory note to refer to 'nicotine-free refill packs' as well.

[8] CBb 9 July 2024, ECLI:NL:CBB:2024:445.

[9] Article 3a of the Act.

since appeared on the market. In 2024, the RIVM identified nicotine-containing, tobacco-free sticks on the Dutch market for the first time.[10] These nicotine sticks bear a strong resemblance to tobacco sticks designed to be heated and are used in the same heating devices. The nicotine sticks contain not only nicotine, but also flavourings, humectants and carrier materials such as cellulose (vegetable fibres), tea leaves or other plant material. When heated, nicotine and flavourings are released, which are inhaled by the user.[11] These sticks often come in delicious flavours and are marketed in an appealing way, for example through attractive packaging.[12]

It appears that, by bringing these products to market, the tobacco industry has sought to circumvent the existing regulations governing conventional tobacco products. This is because the European tobacco legislation only applies to tobacco products and certain related products, such as electronic vapour products, but not (yet) to nicotine products without tobacco. Nor did Dutch legislation impose any requirements in this regard prior to 2025. Tobacco products have long been subject to, amongst other things, an age limit, an advertising ban and, for several categories, a ban on characteristic flavours. As mentioned, a comprehensive set of rules governing nicotine products without tobacco has now come into force in the Netherlands.[13] In addition to the aforementioned total ban on trade in nicotine products without tobacco for oral use, all nicotine products without tobacco are currently also subject to a smoking ban and an advertising ban. For other nicotine products without tobacco, there is also an age limit.

The harmfulness and addictive potential of nicotine products without tobacco
The main ingredient in nicotine products without tobacco is nicotine. Nicotine is an acutely toxic substance that is rapidly absorbed by the body, whether administered through the skin, by mouth or by inhalation. For example, the use of a large amount of nicotine can lead to acute nicotine poisoning with sometimes fatal outcomes. The amount of nicotine and the time taken for it to be absorbed are the determining factors here. Children are a risk group because they are more sensitive to nicotine and have a lower body weight than adults. This enables them to ingest a higher dose of nicotine per kilogram of body weight more quickly, thereby achieving higher concentrations of nicotine in the blood plasma. The main direct effects on the nervous system include dizziness, excessive salivation, an increased and irregular heart rate, as well as elevated blood pressure. The substance also causes a nicotine rush and can cause a burning sensation in the mouth and the gastrointestinal tract. It can also initiate or maintain nicotine addiction. Prolonged use of nicotine may pose an increased risk of cardiovascular disease. Nicotine is also harmful to an unborn fruit, has a detrimental effect on the development of the brains of adolescents and can have adverse effects on the respiratory tract.[14] The RIVM therefore concludes that nicotine products without tobacco are harmful to health. Nicotine, even without tobacco, is harmful, and nicotine products without tobacco currently generally contain enough nicotine to cause an irregular heart rhythm and to induce and sustain nicotine addiction. Given their harmful and addictive effects, the aim of regulating these products is to prevent people from using nicotine products without tobacco. This applies in particular to young people, but also to anyone who has never used nicotine or tobacco products before.

Refill packaging: the container is not the packaging unit
Various requirements apply to the packaging (packaging unit and outer packaging) of electronic vapour products. For example, there is an obligation to place a health warning on the packaging. This is different for refill packaging without a packaging unit (box). Refill packs fall under the category of electronic vapour products. Refill packs in a box are subject to the obligation to display a health warning on the packaging unit (the box). However, this requirement does not apply to the refill packaging itself (usually the bottle containing the liquid). According to the legal definition, a refill pack is “a container holding a nicotine-containing liquid that can be used for refilling an electronic cigarette”[15]. Since the bottle is the container of a nicotine-containing liquid used to refill an electronic cigarette, the CBb considered that the bottle containing the refill liquid must be regarded as the refill pack.[16] When the bottle is placed on the market in a box, the box is the packaging unit (smallest individual packaging of the product). In that case, the health warning

[10] Rijksinstituut voor Volksgezondheid en Milieu. [National Institute for Public Health and the Environment]. Fact sheet: Novel tobacco products that are heated. 2018. URL: https://www.rivm.nl/sites/default/files/2018-11/Publicatie_Nieuwsoortige_tabaksproducten_TG.pdf
[11] Nicotinesticks without tobacco: exceedance of maximum nicotine emission advisory values. RIVM 2025.
[12] Concerns about Levia, a new type of cigarette that does, after all, allow for flavoured smoking. Metro News, 8 August 2024.
[13] Bulletin of Acts and Decrees 2024, 292.
[14] Non-tobacco nicotine products for recreational use; RIVM Briefing Report 2020-0152.
[15] Article 1 of the Act. There are also nicotine-free refill packs, which contain a liquid that does not contain nicotine and which can be used to refill an electronic cigarette.
[16] CBb 9 July 2024, ECLI:NL:CBB:2024:445, paragraph 4.4.

must be printed on the box. This means that, for refill packs sold unpackaged – for example, a single bottle of refill liquid – there is currently no obligation to include the health warning, as there is no packaging in such cases. Similarly, all other requirements that apply to the packaging unit and the outer packaging of electronic vapour products currently do not apply to the external appearance of unpackaged refill packs.

3. Outline of the proposal

Setting limit values for nicotine in nicotine products without tobacco
In view of the harmful effects and addictive potential of nicotine products without tobacco, particularly for young people, this regulation sets limit values for nicotine in tobacco-free nicotine products. The aim is to protect public health, in particular the health of young people, and to reach the smoke-free generation by 2040.

This regulation sets the maximum amount of nicotine that a nicotine product without tobacco may contain. A specific form of nicotine is 6-methylnicotine.[17] For all forms of nicotine, with the exception of 6-methylnicotine, a maximum amount of 0.028 milligrams per nicotine product without tobacco is established. For 6-methylnicotine, a maximum amount of 0.0030 milligrams per nicotine product without tobacco is established. These values correspond to the RIVM advisory values for these substances in nicotine products without tobacco.[18] It is stipulated that nicotine products without tobacco which do not contain 6-methylnicotine may contain a maximum of 0.028 milligrams of nicotine, and that nicotine products without tobacco which do contain 6-methylnicotine – even if only in part – may contain a maximum of 0.0030 milligrams of nicotine, including 6-methylnicotine.

The applicable limit value shall apply per unit of product. Product unit refers to the intended quantity of the relevant nicotine product without tobacco used in a single use session. In the case of a nicotine stick, for example, this refers to a single stick. For products such as steam stones, this refers to the quantity of steam stones corresponding to the expected amount used in a single session. It is up to the Dutch Food and Consumer Product Safety Authority [Nederlandse Voedsel en Warenautoriteit] (hereinafter: NVWA) as a supervisor of the tobacco and smoking goods regulations in order to determine in a specific case the foreseeable amount of use of a nicotine product without tobacco for the intended use. The manufacturer’s instructions are an important indication of what constitutes a realistic quantity of use.

Research methods
For enforcement purposes, this Regulation does not prescribe a method of investigation to determine the quantities of nicotine and 6-methylnicotine in nicotine products without tobacco. It is therefore up to the enforcement authorities to assess the most appropriate method of investigation.

Requirements on packaging materials
The present Regulation also lays down requirements for the appearance of refill packs, so that the appearance of refill packs also meets the same requirements that apply to unit packets and any outside packaging of electronic vapour goods.

Refill packs must therefore bear a health warning. The wording of the health warning differs depending on the presence or absence of nicotine in the refill fluid. The nicotine content and the nicotine release per dose must be indicated on refill packs containing nicotine. In order to ensure a good understanding by the consumer, it must be clearly indicated on nicotine-free refill packs that the product does not contain nicotine. Any other requirements imposed on the unit packet and any outer packaging pursuant to Article 3.10 of the Regulation shall also apply to the refill packaging itself.

In addition, any information about the contents of the refill pack that is relevant to a proper understanding of it must also be stated on the bottle. This ensures that consumers can always access the most important information about the contents of a refill packaging.

Even when refill packaging is sold in a box, it is desirable that requirements are imposed on the refill packaging, as this box is usually thrown away immediately after purchase. From a public health point of view, it is therefore important that both the box and the refill packaging itself meet the same requirements.

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[17] Alkaloid. In: Lewis RA, ed. Dictionary of Toxicology. Lewis Publishers, 1996.
[18] RIVM letter report 2025-0067 J.M.M. Rutten et al.

At the same time as this Regulation, Article 3.10a of the Regulation shall enter into force.[19] Article 3.10a makes standard packaging for electronic vapour products mandatory. These are requirements relating to the packaging unit and outer packaging of electronic vapour products, including the packaging unit and outer packaging of refill packs. In order to ensure that refill packs themselves also have an appearance in the standard colour Pantone 448 C, this Regulation imposes the same requirements on the appearance of refill packs as those imposed on the packaging unit and outer packaging of electronic vapour products under Article 3.10a of the Regulation. By way of derogation from Article 3.10a of the Regulation, a transparent appearance shall also be allowed for refill packs. The same considerations as with regard to the affixing of health warnings to refill packs also apply to the imposition of a standard appearance on refill packs. For example, it is not desirable for the mandatory standard colour of packaging for electronic vapour products to be circumvented by selling refill packs without a packaging unit.

4. Relationship to superordinate legislation

Worldwide

WHO Framework Convention
The WHO Framework Convention on Tobacco Control[20] (hereinafter: Framework Convention) seeks the widest possible international cooperation and participation of all States Parties in order to provide “an effective, appropriate and comprehensive international response to the spread of the tobacco epidemic”.[21] On 27 April 2005, the Framework Convention entered into force for the European part of the Netherlands.

The preamble to the Framework Convention expresses concerns about the worldwide increase in smoking and other forms of tobacco consumption. Parties are encouraged to develop strategies to discourage tobacco use[22] and to limit direct or indirect incentives that encourage the purchase of tobacco products.[23] The Framework Convention also encourages Parties to regard the obligations arising from the Framework Convention as a minimum standard and to adopt more far-reaching measures.[24] The Framework Convention calls on the Parties to take appropriate measures to prevent nicotine addiction.[25] As a result, Parties have the opportunity to regulate themselves on a number of topics that are not explicitly regulated by the Framework Convention, and to develop suitable mechanisms that can reduce the demand for tobacco in the long term. Setting maximum nicotine levels in nicotine products without tobacco, in order to counteract the addictive nature of nicotine products without tobacco, is one of those subjects. In addition, this is in line with the provisions of Article 5(2)(b) of the Framework Convention, which calls on the Parties to take effective legislative, executive, administrative and/or other measures to prevent and reduce tobacco consumption, nicotine addiction and exposure to tobacco smoke.

Setting maximum nicotine levels for nicotine products without tobacco is appropriate, as this will help to limit the addictive effects of harmful products that may trigger or perpetuate nicotine addiction and that may be used as alternatives to tobacco products. The same applies to the requirements regarding the appearance of refill packs. By ensuring that the requirements governing the appearance of refill packs are aligned with those governing the packaging of refill packs and other components of electronic cigarettes, the appeal of electronic cigarettes – particularly to young people – can be curbed more effectively.

European

The Tobacco Products Directive
The Tobacco Products Directive[26] also serves to implement the Framework Convention, the provisions of which are binding on the EU and its Member States. The Tobacco Products Directive aims to harmonise the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products and related products. This

[19] Official Gazette 2026, [PM].

[20] The WHO Framework Convention on Tobacco Control, concluded in Geneva on 21 May 2003 (Treaty Series 2003, 127 and Treaty Series 2004, 269).

[21] Preamble to the Framework Convention.

[22] Article 12(e) of the Framework Convention.

[23] Article 13(4)(c) of the Framework Convention.

[24] Article 13(5) of the Framework Convention.

[25] Article 5(2)(b) of the Framework Convention.

[26] Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC.

is done to improve the functioning of the single market for tobacco products and related products. This is based on a high level of protection of public health, particularly for young people.[27] The Tobacco Products Directive does not provide for a complete harmonisation, so that Member States still have scope to devise their own rules for certain matters.[28]
The Tobacco Products Directive only applies to tobacco products and certain related products, namely electronic cigarettes, refill packs and herbal products intended for smoking.[29] This means that the Tobacco Products Directive does not apply to nicotine products without tobacco, as these are neither tobacco products nor electronic cigarettes, refill packs or herbal products intended for smoking. The term 'electronic vapour products' is explicitly excluded from the definition of nicotine products without tobacco, so that the provisions relating to 'electronic vapour products' – which fall under the Tobacco Products Directive – take precedence in the event that a product would qualify as both an electronic vapour product and a nicotine product without tobacco if this exclusion had not been made. As the Tobacco Products Directive does not apply to nicotine products without tobacco, this regulation concerning the maximum nicotine levels for nicotine products without tobacco is therefore in accordance with European law, provided that it is compatible with primary Union law and does not jeopardise the full application of the Tobacco Products Directive.[30] This means that the present regulation must not, under any circumstances, lead to displays or advertising that promote tobacco consumption, nor must it give rise to any confusion with a tobacco product. This is not the case with the (further) regulation of nicotine products without tobacco.

In addition, the Tobacco Products Directive does not lay down any rules on the appearance of electronic vapour products, including refill packs. On the aspects of tobacco products and electronic vapour products not regulated by the Tobacco Products Directive, Member States may still lay down additional rules within the framework of primary EU law. This includes the requirements relating to the appearance of refill packs.

In the context of primary EU law, the free movement of goods is of particular importance.

The free movement of goods
Both the maximum nicotine levels for nicotine products without tobacco and the requirements regarding the appearance of refill packs could be regarded as quantitative restrictions on imports or measures having equivalent effect within the meaning of Article 34 of the Treaty on the Functioning of the European Union (hereinafter: TFEU). Based on Article 36 of the TFEU, Member States are permitted to introduce restrictions of this kind if they meet a number of conditions[31]. The measure must:
1. be justified by overriding reasons relating to the public interest;
2. be suitable for guaranteeing the realisation of the pursued objective;
3. not go beyond what is necessary;
4. be identifiable and predictable; and
5. applied without discrimination.

Both the setting of maximum nicotine levels for nicotine products without tobacco and the imposition of requirements regarding the appearance of refill packs are, even if they were to constitute a barrier to trade, justified on the grounds of an overriding reason of public interest, namely: the protection of public health. Article 36 TFEU explicitly states that the protection of health is a possible justification. It appears from the case-law of the Court of Justice of the European Union that Member States have a considerable degree of freedom with regard to public health policies and in determining the level of protection.[32] Member States are free to determine their own level of protection. The Dutch government is committed to a high level of protection and aims to achieve a smoke-free generation by 2040, ensuring that young people do not come into contact with nicotine products other than tobacco, which can cause nicotine addiction and act as a gateway to tobacco products.

Maximum nicotine levels for nicotine products without tobacco
The setting of maximum nicotine levels for nicotine products without tobacco is an appropriate means of achieving the aforementioned objective of protecting public health, in particular that of

[27] See, inter alia, Recitals 8 and 21 of the Tobacco Products Directive.

[28] See the scope of application of the Tobacco Products Directive in Article 1.

[29] Article 1(f) of the Tobacco Products Directive.

[30] See consideration 55 of the Tobacco Products Directive.

[31] Judgment of the Court of Justice of 30 November 1995, *Gebhard, ECLI:EU:C:1995:411;* Judgment of the Court of Justice of 4 July 2000, *Haim, ECLI:EU:C:2000:357;* Judgment of the Court of Justice of 1 February 2001, *Mac Quen and Others, ECLI:EU:C:2001:67*.

[32] Judgment of the Court of Justice of 13 July 2004, *ECLI:EU:C:2004:432 (Commission v France)*, paragraph 33.

young people. By setting maximum nicotine levels, users of nicotine products without tobacco are protected from the adverse health effects of the currently high nicotine levels in nicotine products without tobacco, such as addiction, respiratory irritation and an increased heart rate. Setting maximum nicotine levels for nicotine products without tobacco does not go beyond what is necessary to protect users' health, as this is the only way to protect users from exposure to excessive amounts of nicotine and 6-methylnicotine in nicotine products without tobacco.

Requirements regarding the appearance of refill packs
Requirements regarding the appearance of refill packs are necessary because refill packs are not always sold as part of a packaging unit, or because the packaging is discarded immediately after purchase (see section 3.3). It is therefore necessary that the requirements for the appearance of refill packs correspond to the requirements laid down for unit packets and outer packaging of electronic vapour products.

In view of the high level of public health protection pursued by the government and in order to achieve a smoke-free generation by 2040, it is important to reduce the attractiveness of electronic vapour products including refill packs. The requirements regarding the appearance of refill packs do not go beyond what is necessary to achieve the objective, namely to ensure a high level of protection of public health. No more stringent requirements shall be imposed on the appearance of refill packs than on the packaging of electronic vapour products. This regulation prevents refills from not bearing a health warning when they are placed on the market without a unit packet. In addition, this regulation ensures that the standard colour for the packaging of electronic vapour products applies not only to the packaging itself but also to the appearance of refill packs. The regulation making standard packaging for electronic vapour products mandatory shall enter into force at the same time as this regulation. This is particularly important in cases where refill packs are placed on the market without a unit packet. The same applies to the application to refill packs of the requirements already applicable to the unit packet and any outside packaging of electronic vapour goods pursuant to Article 3.10 of the Regulation. These are the requirements applicable to unit packets and outer packaging pursuant to Article 20(4)(b) of the Tobacco Products Directive. This includes, amongst other things, the requirement to state the nicotine content and the batch number, and the ban on references to flavours. In the absence of the batch number, traceability would be jeopardised. Furthermore, consumers are not provided with sufficient information if a list of ingredients and the nicotine delivery per dose are missing. It is important that these requirements also apply to refill packs. Furthermore, from a public health perspective, it is necessary for the health warning to be printed directly on the refill pack itself, as any outer packaging surrounding a refill pack is usually discarded immediately after purchase and the refill pack is stored without this outer packaging. All obligations that must be on a package must therefore also be on the bottle.

The requirement of transparency and predictability is also met, both with regard to maximum nicotine levels for nicotine products without tobacco and requirements for the appearance of refill packs. After all, this regulation is being put out for public consultation online and will be published in the Government Gazette in due course once it has been adopted.

The new requirements will apply, both to nicotine products without tobacco and to refill packs, to all products that are or will be placed on the market in the Netherlands, regardless of whether the products are manufactured in the Netherlands or elsewhere, thereby ensuring that the measures are applied without discrimination. Based on the foregoing, the measures taken are deemed to be compliant with the European rules concerning the free movement of goods.

5. Notification

Directive (EU) 2015/1535 addresses the content of the technical regulation, not the legal possibility of adopting technical regulations. The amendment, which concerned only the establishment of a basis for delegation, was not notified. That scheme, which is based on the legal basis laid down in that decree, is of course notified. [PM]

6. Impact on implementation and enforcement

On 10 March 2026, the Dutch Food and Consumer Product Safety Authority (NVWA) was presented with this scheme for a compatibility and enforceability test. The NVWA has concluded that the amendment to the regulations is enforceable, practicable and fraud-proof. However, the NVWA does make some recommendations to clarify certain provisions.

The NVWA notes that it should be clarified that a refill pack may constitute a packaging unit if it is sold as a single bottle, without any further packaging. However, this reading does not appear to be

correct. It follows from the CBb's ruling, which is cited, amongst other places, in paragraph 2.2 above, that a refill pack cannot constitute a packaging unit, because the refill pack is the product – 'the container' – itself.

When a refill pack is placed on the market in a box, that box constitutes the smallest individual package and, therefore, the packaging unit. If a refill pack is placed on the market without a box, the bottle is the container. Since, in that case, there is no separate packaging around the refill pack, there is no packaging unit.

As it is considered undesirable that, in such cases, the same requirements should not apply to the bottle as to a packaging unit, these requirements are, under the present regulation, also declared to apply to the refill packaging itself, namely the bottle.

The NVWA recommends that refill packs without a box – i.e. the bottle itself – should also state the batch number, the list of ingredients and the nicotine delivery per dose, in order to improve traceability. These requirements are added in Article 2.13, paragraphs 1 and 2.

In addition, the NVWA is asking whether so-called 'pods' fall within the scope of this scheme. Pods are cartridges, not refill packs. They are not used to refill the liquid in the container of an electronic cigarette, but are placed as a whole in the electronic cigarette. Cartridges are part of an electronic cigarette and are not refill packs. Therefore, the requirements for the appearance of refill packs set out in this Regulation do not apply to pods.

Furthermore, the NVWA requests that the wording of the warning in Article 2.14, paragraphs 1 and 2, should not be limited to non-smokers, but should be extended to include smokers. This is not being addressed. The warning text is taken from Article 20(4)(b)(iii) of the Tobacco Products Directive, which stipulates that it must appear on packaging units and outer packaging of electronic cigarettes and refill packs. Any deviation from this rule with regard to individual refill packs is undesirable.

The NVWA also considers that discussions may arise about the open standard on the expected quantity of use of a non-tobacco nicotine product. The explanatory notes have been clarified on this point.

Finally, for the sake of uniformity and clarity, the NVWA recommends that Article 2.13, first paragraph, be amended in such a way that it is clear that the nicotine content must be indicated in mg per ml. This has been adjusted in the present scheme.

7. Impact on regulatory burden

General

This amendment does not affect the regulatory burden of citizens and companies. However, the scheme does impose a regulatory burden on products, importers and retailers. First, they must take cognisance of the rules at issue. This involves costs associated with taking note of the information. These one-time familiarisation costs are estimated at EUR 54 per hour for producers, importers and retailers of nicotine products without tobacco and of refill packs. The number of producers and importers of nicotine products without tobacco is unknown. The number of retailers is estimated at 1,600. How many of them are also selling nicotine products without tobacco is not known. The number of producers and importers placing electronic vapour products on the market has most likely decreased following the sales ban in supermarkets[33], the online sales ban[34] and the ban on vapes with flavours other than tobacco, but the exact number is unknown. It is estimated that the number of specialist shops selling exclusively electronic vapour products has decreased and that these shops have started selling tobacco products in addition to electronic vapour products. As the exact numbers of producers, importers and retailers are not known, no figures have been included in the table below, which sets out the regulatory burden.

Nicotine products without tobacco

[33] Bulletin of Acts and Decrees 2024, 89.

[34] Bulletin of Acts and Decrees 2023, 141.

The total number of producers, importers and retailers placing nicotine products without tobacco on the market is unknown. For this reason, no numbers are given in the table.

For producers, this regulation leads to an increase in regulatory burden. The ingredients in nicotine products without tobacco will have to comply with the prescribed maximum levels. Products with a higher nicotine content may no longer be placed on the market. This means that the product and the production process will need to be adapted. As regards the product, the recipe needs to be adjusted to reach the new nicotine concentration. In addition, laboratory tests and quality control checks must be carried out. Furthermore, the production process will be adjusted. In some cases, dosing pumps or mixing software will need to be recalibrated for this purpose. Labels and packaging will also have to be adapted (new nicotine designation). Finally, this change will have to be uploaded to the EU CEG portal. The time producers spend on this and the investments they must make cost money. These are one-off costs. The costs and timeframes shown in the table are indicative and based on an estimate.

Action (one-off)	Who	Time	Cost	Q
Knowledge costs	Producers, importers, retailers	1 hour		
Edit recipe	Producers	1-2 days	Included in the costs listed below	
Laboratory testing/quality control	Producers	2 weeks		
Adjusting the production process, including labelling and packaging	Producers	1-2 weeks		
Administrative costs, such as uploading to the EU CEG	Producers	2 days		
Overall cost	Producers			

Refill packs
The number of manufacturers, importers and retailers placing refill packs on the market is also unknown. For this reason, no figures are given in the table. For producers, this regulation leads to an increase in regulatory burden. The production process must be adjusted once. Costs are also incurred to convert printing equipment. Furthermore, it will be necessary to make adjustments to the software and the software will be tested. A retailer will have to pay some attention to purchasing, stock management and sales. A total of 6 hours has been allocated for this. The hourly rate for converting the pressure equipment is difficult to quantify and has been determined on a general basis. The cost of modifying the software is estimated at between €60 and €90 per hour, as is the cost of testing it. The time required for this is estimated at 6–10 hours. The costs and timeframes shown in the table are indicative and based on an estimate.

Action (one-off)	Who	Time in hours	Cost per hour	Q
Knowledge costs	Producers, Importers, Retailers			
Conversion of printing equipment	Producers			
Software adaptation	Producers			
Software testing	Producers			
Adjustment of procurement and stock management	Retailers			
Overall cost	Producers			

All the consequences of regulatory measures are inevitable and necessary to ensure that a healthy generation is raised, in which young people and other vulnerable groups are protected not only

from the temptation to take up smoking, but also from using nicotine products without tobacco or e-cigarettes.

The Advisory Board on Regulatory Burden [Adviescollege toetsing regeldruk] (ATR) has assessed the scheme in terms of its impact on the regulatory burden. The ATR did not select this case for a formal opinion because it does not have a significant impact on regulatory burden.

8. Online consultation

Via www.internetconsultatie.nl/, from [PM] 2026 to [PM] 2026, everyone was given the opportunity to respond to a draft of the present amendment to the Regulation and this explanatory memorandum. [PM]

9. Entry into force

The intended date of entry into force is 1 January 2027. Requirements for refill packs and nicotine-free refill packs shall be subject to a sell-off period equal to the sell-off period for the standard packaging requirements for electronic vapour products. Refill packs and nicotine-free refill packs produced or released for free circulation before 1 January 2027 may therefore continue to be placed on the market until 1 January 2028.

Explanatory notes for individual articles

Article I, Part A
Article I, Part A, adds three articles to the Regulation:

Article 2.13
Article 2.13 provides that the requirements laid down in Article 3.10 of the Regulation for the unit packet and any outside packaging of electronic vapour goods also apply to the appearance of[35] refill packs and nicotine-free refill packs.

The first paragraph stipulates that refill packs must be marked with the nicotine content and nicotine delivery per dose. Refill packs without nicotine must state that the product contains no nicotine, so that consumers clearly understand it is a nicotine-free refill pack. In addition, the second paragraph sets out the requirement to print a list of all the product's ingredients in descending order of weight, together with the batch number, on refill packs and nicotine-free refill packs. These requirements have been taken over from Article 3.10.

Furthermore, the third paragraph provides that the recommendation to keep the product out of reach of children applies to refill packs containing nicotine, even if this indication is not required under Regulation (EC) No 1272/2008.

Article 2.13, fourth and fifth paragraphs, provide that statements which, pursuant to Article 3.10, may not appear on a unit packet or any outside packaging of electronic vapour goods may not appear on a refill pack either. These latter requirements apply to the packaging of refill packs pursuant to Article 3.10(3), which refers to Article 20(4)(b)(ii) of the Tobacco Products Directive. For the packaging of nicotine-free refill packs, to which the Tobacco Products Directive does not apply, these requirements apply pursuant to Article 3.10(4). There is no substantive difference between the requirements imposed on the packaging of refill packs pursuant to Article 3.10(3) and the requirements imposed on the packaging of nicotine-free refill packs pursuant to Article 3.10(4). Because the Tobacco Products Directive does not regulate the appearance of refill packs and nicotine-free refill packs, the requirements in the new Article 2.13 have been set out for both refill packs and nicotine-free refill packs, as well as in Article 3.10(4) for the packaging of nicotine-free refill packs (which are also not regulated by the Tobacco Products Directive). In accordance with the amendment to Article 3.10(4)(c), Article 2.13(3)(c) also provides for a prohibition on any element or feature that refers to a scent; for further details, see the article-by-article commentary on Article I, Part B, below.

Article 2.14

[35] In accordance with Article 1 of the Act, the term 'refill pack' refers to refill packs containing a nicotine-containing liquid.

Refill packs must in addition be marked with the same warning text pursuant to Article 2.14 as on unit packets of electronic vapour products. For refill packs with nicotine-containing liquid, the warning text shall be: ‘This product contains the very addictive substance nicotine. Their use is not recommended for non-smokers’ (first paragraph); for refill packs containing nicotine-free liquid, the warning text is: ‘This product harms your health. Its use is not recommended for non-smokers’ (second paragraph). The warning messages must comply with the requirements set out in Article 20(4)(c) of the Tobacco Products Directive. As the Tobacco Products Directive refers to ‘unit packet and outer packaging’, and as these do not apply in the case of refill packs and refill packs without nicotine, the requirements set out in Article 20(4)(c) of the Tobacco Products Directive have been incorporated into Article 2.14(3). In addition, Article 2.14(4) stipulates that refill packs must have a standard appearance in the standard colour Pantone 448C, which corresponds to the standard colour of packaging for electronic vapour products, on the understanding that a refill pack or a nicotine-free refill pack may also be transparent instead of the colour Pantone 448C. For details of the standard design of refill packs and nicotine-free refill packs, please refer to Article 3.10a of the Regulation, which sets out the standard packaging requirements for electronic vapour products.[36] Article 3.10a shall enter into force at the same time as this Regulation. The standard colour and other information referred to in Article 3.10(2) may be displayed on a refill pack or a nicotine-free refill pack by means of a sticker, provided that the sticker cannot be removed. Similarly, the health warning does not need to be printed on the refill pack; it must be affixed in such a way that it cannot be removed. A non-removable sticker may therefore also be used for the health warning.

Article 2.15

Article 2.15 regulates the maximum nicotine content for nicotine products without tobacco. All forms of nicotine fall under the legal definition of ‘nicotine’. RIVM has conducted research on the standard form of nicotine and on 6-methylnicotine. A different limit value has been set for these two forms of nicotine. It is therefore regulated that an NZT containing only forms of nicotine other than 6-methylnicotine may contain up to 0.028 milligrams of nicotine (in any form) per product unit (Part a). Nicotine products without tobacco in which the nicotine component consists wholly or partly of 6-methylnicotine may contain no more than 0.0030 milligrams of nicotine per unit of product (Part b). In both cases, the mentioned limit concerns the maximum nicotine content. In other words, the limit value is a cumulative value and applies to the sum of the levels of all forms of nicotine present in the respective nicotine product without tobacco.

Article I, Part B

Article 13(1)(c) of the Tobacco Products Directive prohibits elements and characteristics on unit packets and outer packaging that refer to “a taste, flavourings or other additives, or the absence thereof”. It can be inferred from other language versions (English, German and French) that Article 13(1)(c) of the Tobacco Products Directive prohibits elements and characteristics which refer to “a taste, smell or flavourings or other additives, or the absence thereof”. Article 3.10(4), point (c) (like Article 2.13, third paragraph, point (c); see the article-by-article commentary on Article I, part A, above) is based on Article 13, first paragraph, point (c), of the Tobacco Products Directive. Article 3.10(4), point c, therefore states that the prohibition laid down in that section also applies to an element or characteristic that refers to an odour.

Article I, Part C

Unit packaging and outer packaging of electronic vapour products must have a standard appearance from the same time that the mandatory standard appearance of refill packs and nicotine-free refill packs comes into force. The requirements for the appearance of refill packs and nicotine-free refill packs are therefore aligned with the one-year sell-out period that also applies to unit packaging and outer packaging of electronic vapour products. Consequently, refill packs and nicotine-free refill packs manufactured or released for free circulation before 1 January 2027 may continue to be placed on the market until 1 January 2028, provided they comply with the regulations in force on 31 December 2026, i.e. prior to the entry into force of the present regulations.

The Minister for Public Health,
Welfare and Sports,

[36] Official Gazette 2026, [PM].