

Rozporządzenie Sekretarza Stanu ds. Zdrowia,  
Opieki Społecznej i Sportu  
zmieniające rozporządzenie w sprawie wyrobów tytoniowych  
i wyrobów przeznaczonych do palenia w związku z  
wprowadzeniem standardowego opakowania papierosów i  
tytoniu do samodzielnego skręcania papierosów

1. -----IND- 2019 0479 NL- PL- ----- 20191015 --- --- PROJET  
Sekretarz Stanu ds. Zdrowia, Opieki Społecznej i Sportu,

w odniesieniu art. 3 ust. 4 pkt 1 i pkt 2 decyzji o wyrobach tytoniowych i  
wyrobach przeznaczonych do palenia;

niniejszym zarządza co następuje:

#### **ARTYKUŁ I**

W rozporządzeniu w sprawie wyrobów tytoniowych i wyrobów przeznaczonych do  
palenia wprowadza się następujące zmiany:

A

Do art. 3.7 dodaje się osiem nowych ustępów w brzmieniu:

3. Opakowanie jednostkowe lub opakowanie zewnętrzne papierosów lub tytoniu do  
samodzielnego skręcania papierosów są wykonane z materiałów ciągłych, nie  
zawierają części przezroczystych ani efektów dźwiękowych i są barwione od  
wewnątrz kolorem Pantone 448 C lub białym w matowym i jednolitym  
wykończeniu.

4. Poza przepisami ustępu 3 opakowanie jednostkowe lub opakowanie zewnętrzne  
papierosów lub tytoniu do samodzielnego skręcania papierosów może:

a. zawierać wewnątrz folię, która okrywa produkty w celu zachowania świeżości,  
pod warunkiem, że folia jest niezadrukowana, ma matowe i jednolite wykończenie  
i jest całkowicie biała lub srebrna na zewnątrz i biała od wewnątrz;

b. zawierać folię jako część opakowania wewnętrznego, która uszczelnia  
opakowanie, pod warunkiem że folia jest niezadrukowana, ma matowe i jednolite  
wykończenie i jest srebrna;

c. zawierać kopertę z niezadrukowanego, bezbarwnego i przezroczystego celofanu  
w jednolitym wykończeniu, która może zawierać celofanowy pasek, pod  
warunkiem że celofanowy pasek:

1°. nie jest szerszy niż trzy milimetry;

2°. biegnie w tym samym kierunku czytania co ostrzeżenie tekstowe z mieszanego  
ostrzeżenia zdrowotnego; i

- 3°. jest przezroczysty lub czarny, którego odcinek o długości nie większej niż piętnaście milimetrów może być natomiast przezroczysty lub czarny;
- d. zawierać pasek samoprzylepny, aby opakowanie mogło być ponownie zamykane, pod warunkiem, że ten pasek samoprzylepny jest niezadrukowany, bezbarwny i przezroczysty oraz ma jednolite wykończenie.
5. Część paczki i opakowania zewnętrznego papierosów lub tytoniu do samodzielnego skręcania papierosów z ostrzeżeniem zdrowotnym nie zawiera efektów dźwiękowych i jest na zewnątrz zabarwiona kolorem Pantone 448 C w matowym i jednolitym wykończeniu.
6. Poza przepisami ustępu 5 część paczki i opakowania zewnętrznego papierosów lub tytoniu do samodzielnego skręcania papierosów, która nie zawiera ostrzeżenia zdrowotnego może:
- a. zawierać nazwę marki i wariant marki na zewnątrz, pod warunkiem, że tekst:
- 2°. is rendered in the standard Helvetica font without formatting variants;
- 3°. is rendered in the colour Pantone Cool Gray 2C with a matt and uniform finish;
- 4°. contains only the letters of the alphabet, numbers or the ampersand symbol;
- 5°. contains capital letters only for the first letter of each word;
- 6°. contains at most one space between each word;
- 7°. is rendered in a maximum character size of 14 for the brand name and a maximum character size of 10 for the brand variant;
- 8°. of the brand variant is included directly under the brand name and runs centred with the brand name and in the same reading direction as the text warning of the combined health warning;
- 9°. of the brand name is not longer than one line;
- 10°. of the brand variant is not longer than one line.
- b. indicate not more than once the number of cigarettes that are in the packaging or the weight of a pack of roll-your-own tobacco in grams on the outside, provided that the text:
- 1°. is rendered in the standard Helvetica font without formatting variants;
- 2°. is rendered in the colour Pantone Cool Gray 2C with a matt and uniform finish;
- 3°. is rendered on the package in a character size of 10;
- 4°. is rendered on the outer packaging in a character size of 14;
- 5°. runs in the same reading direction as the text warning from the combined health warning;
- 6°. indicates the number of cigarettes using figures;
- 7°. indicates the number of grams of roll-your-own tobacco using figures, followed by the letter g;
- c. include the name, the address, the email address and the telephone number of the manufacturer, provided that the text:
- 1°. appears not more than once and is neither on the front of the package nor on the outer packaging;
- 2°. is rendered in the standard Helvetica font without formatting variants;
- 3°. is rendered in the colour Pantone Cool Gray 2C with a matt and uniform finish;
- 4°. is rendered in a maximum character size of 10;
- 5°. contains only the letters of the alphabet, numbers or the ampersand symbol or, if there is an email address, an @ sign; and
- 6°. contains capital letters only for the first letter of each word.
- d. include a calibration mark on the outside that is as inconspicuous as possible;
- e. include not more than one bar code, provided that the bar code:
- 1°. appears neither on the front of the package nor on the outer packaging;
- 2°. is rendered in the colours black and white or in Pantone 448 C and white with a matt and uniform finish; and

3°. does not form a design, pattern, image or symbol that is recognisable as anything other than a bar code.

7. In the case of roll-your-own tobacco packaging in the form of a pouch, the brand name and the brand variant referred to in paragraph 6(a) can, contrary to what is provided for in that subparagraph after 1°, be included not more than once on the front, back and inside of the flap.

8. In the case of cylindrical roll-your-own tobacco packaging, the information referred to in paragraph 6(a), (c) and (e) can, contrary to what is provided for in those subparagraphs after 1°, be included not more than once on:

- a. the lid of the packaging;
- b. the bottom of the packaging, and
- c. on the curved surface of the packaging, the brand name and brand variant being included on the side opposite the side where the name, the address, the email address and telephone number of the manufacturer, and the bar code are included.

9. If an outer packaging contains multiple packages, the weight of the roll-your-own tobacco in grams or the number of cigarettes that are in a single package can, as a supplement to paragraph 6(b), be followed by an x symbol and then the number of packages in figures.

10. This article applies without prejudice to the requirements laid down by or under Articles 4a and 4h for the placement of a unique identification code and security feature on a package.

B

In Article 3.7a, after paragraph 6, a paragraph is inserted with the following text:

7. This Article does not apply to cigarettes and roll-your-own tobacco.

C

In Article 7.3, after paragraph 6, a new paragraph is inserted with the following text:

7. A package or outer packaging for cigarettes or roll-your-own tobacco that complies with the Tobacco and smoking products decree and the Tobacco and smoking products order in the version in force on 30 June 2020 and that is manufactured or released into free circulation before 1 July 2020 may be marketed until 1 July 2021.

## **ARTICLE II**

This order will come into force on 1 July 2020.

## **Explanatory note to the amendment to the Tobacco and smoking products order concerning standard packaging for cigarettes and roll-your-own tobacco**

### **I General section**

#### **1. Introduction**

Smoking is a serious addiction with very harmful consequences on health and is the principal cause of mortality and disease. Every 30 minutes, someone dies from the effects of smoking.<sup>1</sup> 80% of all smokers started smoking before turning 18. In the National Prevention Agreement<sup>2</sup>, it was agreed that efforts will be made to achieve a smoke-free generation by 2040. This means that, by 2040, no more young people will smoke and that the number of smokers among Dutch persons who are 18 or older will have been reduced to less than 5%.

An initial assessment by the Dutch National Institute for Public Health and the Environment [Rijksinstituut voor Volksgezondheid en Milieu] (hereinafter referred to as 'RIVM') of the possible impact of the National Prevention Agreement has shown that the objective to achieve a smoke-free generation is feasible if a tobacco control policy is focused on that consists of several measures that relate to each other.<sup>3</sup> These measures consist of, among other things, the introduction of the standard packaging; the display ban; the extension of the ban on smoking and the advertising ban; an increase in excise duties, the use of multiannual campaigns; and accessible and available care services to help people stop smoking. Countries with decreasing smoking prevalence have also used a coherent approach of this kind over several years. These measures are aimed at preventing tobacco products from being attractive, accessible and available to young people, but also to other vulnerable groups such as smokers who want to stop and ex-smokers. This will protect young people and other groups from being tempted to smoke and from being exposed to passive smoking. Since I want to achieve a smoke-free generation, I will follow the RIVM's advice. This ministerial order lays down standard packaging for cigarettes and roll-your-own tobacco.

The explanatory note to the decree amending the Tobacco and smoking products decree concerning the introduction of standard packaging for cigarettes and roll-your-own tobacco (hereinafter referred to as 'decree') outlines in detail the objectives, backgrounds and arguments for the introduction of standard packaging.<sup>4</sup> The most important elements of this measure will be briefly discussed below.

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<sup>1</sup> *Dutch Public Health Foresight Study 2018*, RIVM, June 2018. See also: [www.rivm.nl/enwww.volksgezondheidenzorg.info](http://www.rivm.nl/enwww.volksgezondheidenzorg.info), search term: 'public health foresight study 2018' and [www.rivm.nl/enwww.volksgezondheidenzorg.info](http://www.rivm.nl/enwww.volksgezondheidenzorg.info), search term: 'smoking and numbers'.

<sup>2</sup> Parliamentary Paper 2018/19, 32793, No 339, p. 13 and see also: [www.government.nl](http://www.government.nl), search term: national prevention agreement.

<sup>3</sup> *Quickscan mogelijke impact Nationaal Preventieakkoord*, RIVM, November 2018. Annex to Parliamentary Paper 2018/19, 32793, No 339. See also: [www.rivm.nl/en](http://www.rivm.nl/en), search term: 'quickscan impact national prevention agreement'.

<sup>4</sup> Annex to Parliamentary Paper 2018/19, 32011, No 69. [PM refer to Bulletin of Acts and Decrees version later].

The WHO Framework Convention on Tobacco Control (hereinafter referred to as 'the Framework Convention')<sup>5</sup> requires the parties to take measures concerning tobacco product packaging (Article 11) and provides an incentive for parties to consider prescribing standard packaging for tobacco products. Internationally, these requirements are also known as the 'plain packaging' requirements. Great importance is attached to standard packaging requirements because they can increase the visibility and effectiveness of the health warnings on cigarette packs and limit the options that manufacturers have to tempt and mislead consumers.

A recent study<sup>6</sup> about tobacco products evaluating 51 validated scientific studies has shown that there is enough evidence to establish that both young people and adults find neutral packaging less attractive than brand packaging, that the flavour and quality of the product are judged as being lower, that these products are judged as being more harmful than products with brand packaging if the neutral product is darker in colour and that there are indications that young people are less inclined to start smoking.<sup>7</sup> The study suggests that there is evidence that the neutral packaging can contribute to a decrease in smoking prevalence. Neutral packaging therefore ultimately has an impact on smoking behaviour. All scientific findings regarding the effects of standard packaging have been gathered by the Trimbos Institute in the Generic Tobacco Packaging (Generieke Tabaksverpakkingen) fact sheet, a new version of which was created in 2019.<sup>8</sup> This fact sheet confirms the abovementioned results. In addition, it was concluded that there are indications that standard packaging decreases the intention of buying tobacco and that the standard packaging encourages smokers to smoke less or to stop smoking altogether.

## 2. Outline of changes

In addition to the mandatory combined health warning (a picture combined with a warning and a reference to the available help to stop smoking), the general warning and the information message on the packaging, 35% of the front and back of the packaging currently remains for brand expressions. This allows, among other things, manufacturer information, bar codes, word trade marks and logos to be placed on the top and bottom, but also on the sides next to the general warning and information message. However, brands are an important means by which companies can distinguish their products from those of other manufacturers. Brands also have an advertising and marketing function. For this reason, the introduction of uniform standard packaging further limits the freedom that manufacturers have to use the space not covered by the combined health warning, general warning and information message for advertising and marketing purposes. For further details on this point, I would refer to paragraph 3, Standard packaging, of the explanatory note to the decree concerning the introduction of standard packaging for cigarettes and roll-your-own tobacco.

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<sup>5</sup> The WHO Framework Convention on Tobacco Control adopted in Geneva on 21 May 2003 (Treaty Series of the Kingdom of the Netherlands 2003, 127 and Treaty Series of the Kingdom of the Netherlands 2004, 269).

<sup>6</sup> Cochrane: McNeill, A., Gravely, S., Hitchman, S. C., Bauld, L., Hammond, D., & Hartmann-Boyce, J. (2017). Tobacco packaging design for reducing tobacco use (Review).

<sup>7</sup> Cochrane: McNeill, A., Gravely, S., Hitchman, S. C., Bauld, L., Hammond, D., & Hartmann-Boyce, J. (2017). Tobacco packaging design for reducing tobacco use (Review). See 'Main Results' in Cochrane, p. 2.

<sup>8</sup> *Factsheet generiek tabaksverpakkingen (plain packaging)*, Trimbos, June 2019. See also: [www.trimbos.nl/english](http://www.trimbos.nl/english), search term: 'fact sheet generic tobacco packaging'.

Standard packaging is characterised by the overall absence of word and picture trade marks (a combination of letters and design) and logos. In addition to the mandatory general warning, the information message and the combined health warning, the excise stamp and the security feature, standard packaging can include only the brand name, the brand variant, the manufacturer information, the calibration mark and the bar code in a defined colour, font and font size. The standard packaging achieves uniformity in the appearance of cigarette and roll-your-own tobacco packaging, thus keeping advertisement for these tobacco products via the packaging to a minimum.

Colours and logos can no longer be used to attract special attention to the product and tempt young people and other vulnerable groups to smoke.

### **3. Background and context**

This ministerial order specifies in detail the delegation basis set out in Article 3.4 of the decree, which includes prescribing standard packaging for cigarettes and roll-your-own tobacco, by establishing technical requirements for this packaging. The marketing of packaging for these tobacco products is thus limited such that only the brand name and brand variant can be indicated.

The current list of prohibited expressions in Articles 3.7 and 3.7a in the version in force before the entry into force of this order is exhaustive. As a result, anything that is not explicitly prohibited may currently still be affixed to standard packaging. However, since the entry into force<sup>9</sup> of the current Tobacco and smoking products order (hereinafter referred to as 'order'), new packaging designs have been in circulation that, because of their colour scheme, make a sustainable and healthier impression. It is therefore not inconceivable for tobacco manufacturers to come up with other attractive elements that were not provided for by the current legal restrictions and place them on packaging. Packaging with a 'sustainable or responsible' appearance is thus currently in circulation. This gives rise to the risk that young people will still be tempted to use tobacco products because of these elements. For this reason, this order explicitly specifies what is still permitted. Anything that is not specified in this order is therefore prohibited.

The new neutral packaging requirements implemented by this amending order do not negate the requirements laid down in Articles 4a and 4h of the Tobacco and Smoking Products Act (hereinafter referred to as 'TSPA').<sup>10</sup> The requirements provide that tobacco product manufacturers and importers must affix a unique identification mark and security feature to all tobacco product packages that are marketed. These requirements apply without prejudice to the new neutral packaging requirements.

### **4. Packaging requirements**

#### *I General requirements*

This amending order lays down the colour of the package and outer packaging of cigarettes and roll-your-own tobacco: Pantone 448 C with a matt finish. This colour is a mixture of dark brown, olive green and grey and, according to a study conducted in Australia by academics and commercial market researchers,

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<sup>9</sup> Date of entry into force 1 July 2018 for tobacco products other than cigars, but including cigarillos and 1 July 2019 for cigars (Government Gazette 2018, No 23779).

<sup>10</sup> *Parliamentary Papers II* 2018/19, 35 204, Nos 2 and 3.

provokes a certain disgust as compared with other colours.<sup>11</sup> This colour appears to be so unappealing that it increases the awareness of the harmfulness of a product. So far, all other countries in which plain packaging has been introduced have chosen this colour for the package and outer packaging of cigarettes and roll-your-own tobacco. Moreover, it is prohibited to place brand images on the package and outer packaging of cigarettes and roll-your-own tobacco. This is the principal characteristic of the standard packaging. The object of these requirements is to limit any marketing opportunities with regard to the product. The colour of the inside of the package's packaging is thus exclusively the colour Pantone 448 C or white with a matt and uniform finish. The same applies to the inside of the outer packaging of cigarettes and roll-your-own tobacco.

Furthermore, the foil on the inside of the package and outer packaging may only consist of the colours white and silver. This will be discussed in greater detail in the article-specific explanatory notes. The choice of the specific colours white and silver is based on the fact that tobacco manufacturers already seem to be using this colour combination at the moment. Furthermore, the cellophane surrounding the outside of the package and outer packaging may only consist of transparent cellophane. It must not be coloured or printed and can contain a transparent or black cellophane strip.

### *II Requirements concerning content information*

To prevent the information about the content of the packaging from attracting attention, this amending order also lays down rules concerning how the content information is indicated. Thus, only the number of cigarettes contained in the packaging can be printed on the front of the outside packaging or package. Additional information or other indications regarding the number of cigarettes are not permitted. Furthermore, the weight of the roll-your-own tobacco in grams can be indicated not more than once on the outer packaging of the package or on the outer packaging of roll-your-own tobacco. The weight is expressed in numerical form followed by the letter 'g'. Moreover, only the standard Helvetica font can be used to indicate the number of cigarettes and the weight of the roll-your-own tobacco. The text must run in the same reading direction as the combined health warning, and the font size must not be larger than 10 on the package. The text on the outer packaging must not be larger than size 14 point. These requirements are also in line with the regulations of other countries. Thus, it is ensured that the package and the outer packaging look as neutral and uniform as possible, thus attracting as little attention to them as possible.

### *III Requirements for the brand name and brand variant*

Attempts have also been made to achieve consistency with the regulations of other countries when it comes to indicating the brand name and brand variant on the package and the outer packaging of cigarettes and roll-your-own tobacco in order to ensure that the packaging looks as neutral and uniform as possible, thus attracting as little attention to it as possible. For this reason, the text of the brand name and brand variant may only contain the letters of the alphabet, numbers or the ampersand symbol (the & symbol). Furthermore, only the first letter of each word of the brand name and brand variant can be a capital letter. The rest of the letters can only be lower-case letters. Here too, the prescribed standard Helvetica

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<sup>11</sup> Research presented at The Australian Market & Social Research Society 45th National Conference 'Dangerous' on the 6th - 8th of September 2017.

font in Pantone Cool Gray 2C with a matt and uniform finish is based on the font used in the countries that have already introduced neutral packaging. Another requirement that has been adopted is that the brand name and brand variant must not be longer than one line and that there must not be more than one space between the words that make up the brand name and brand variant. The font and the colour of the brand name and brand variant are subject to the same requirements as those concerning the indication of the number of cigarettes and the weight of the roll-your-own tobacco (see paragraph 4, part II, 'Requirements concerning content information').

The brand name and brand variant may be placed on the front, top and bottom of the package and outer packaging of cigarettes not more than once and must be centred and run in the same reading direction as the combined health warning.

## **5. International perspective**

### *Worldwide tobacco control policy*

In order to help achieve as much uniformity as possible in the appearance of standard packaging worldwide, the criteria for standard packaging for cigarettes and roll-your-own tobacco were developed in line with the rules for standard packaging applicable in Australia, New Zealand, Norway, Ireland, Hungary, Belgium, Great Britain and France. Standard packaging for cigarettes and roll-your-own tobacco has recently been introduced in these countries. As is the case in the Netherlands, the neutral packaging requirements in all of these countries are part of a broader package of coherent measures designed to prevent tobacco use.

Neutral packaging for cigars and e-liquids will be introduced at a later stage. It is envisaged that this will take effect in 2022. Ireland, Australia and New Zealand have also introduced neutral packaging for cigars. The experience of these countries will be taken into account when determining the requirements for cigars and the period for entry into force. Time will also be taken to lay down appropriate measures for e-liquid packaging.

### *Free movement*

In my view, the neutral packaging requirements are in line with the WHO Framework Convention on Tobacco Control, Directive 2014/40/EU<sup>12</sup> (hereinafter referred to as 'Tobacco Products Directive'), judgements by the European Court of Justice, the Treaty on the Functioning of the European Union, the Agreement on Trade-Related Aspects of Intellectual Property Rights and in accordance with the European Convention on Human Rights. For further details, see paragraph 6 of the explanatory note to the decree.

Article 24(2) of the Tobacco Products Directive allows the Netherlands to, in principle, maintain or introduce detailed packaging rules for all tobacco products marketed in the Netherlands for the sake of public health and taking into account the high level of public health protection pursued by the Tobacco Products Directive. These measures must be proportional and must not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. Article 24(2) of the Tobacco Products Directive thus constitutes a concrete

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<sup>12</sup> Directive 2014/40/EU of the European Parliament and the Council of 3 April 2014 on the approximation of laws, regulations and administrative provisions of Member States concerning manufacture, presentation and sale of tobacco and tobacco-related products, and repealing Directive 2001/37/EC (OJ L 127, 2014).

application of the principle of the free movement of goods<sup>13</sup>, meaning that an assessment on the basis of Article 24 is sufficient.<sup>14</sup> The packaging requirements specified in this order are justified with a view to protecting public health and suitable for achieving the desired objective. It is a detailed order that lays down requirements for (almost) every aspect of design so that packaging can only be distinguished by means of the brand name and brand variant. However, no less restrictive alternative that can achieve the same goal is conceivable.

The additional packaging requirements laid down by this order are based on the (broader) comprehensive tobacco control policy that is being pursued by the government because smoking is very harmful to health. As already indicated in paragraph 1 of this explanatory note, research by, inter alia, the Trimbos Institute has shown that tobacco product packaging can be designed in such a way that it increases the attractiveness of the product and influences the behaviour of consumers, including in particular, but not exclusively, young people. The neutral packaging requirements as set out in this order thus constitute an appropriate means of achieving the desired objective. In this respect, additional requirements aimed at making cigarette and roll-your-own tobacco packaging less attractive are also necessary. These requirements are also the result of a weighing up of interests in which a reasonable transitional period in the form of a clearance sale arrangement is made, allowing manufacturers to adapt their production process to the new rules and existing stocks to be sold. This point will be explained in even greater detail in the article-specific explanatory notes of this explanatory note (section II, part C). Lastly, the additional packaging requirements apply to all cigarettes and roll-your-own tobacco marketed in the Netherlands or about to be marketed in the Netherlands, meaning that the regulation is non-discriminatory. Based on the above, I deem this order necessary, proportional and commensurate as well as in accordance with Article 24(2) of the Tobacco Products Directive.

## **6. Notification**

The draft version of this order has been notified to the European Commission under Article 5(1) of Directive (EU) 2015/1535. Notification to the European Commission is required, as Article I of this order may contain technical provisions as defined by Directive (EU) 2015/1535. Following this notification

## **7. Impact on implementation and enforcement**

The order has been submitted to the Dutch Food and Consumer Product Safety Authority [Nederlandse Voedsel- en Warenautoriteit] (NVWA) for the implementation and enforcement test. The NVWA is of the opinion that the order is enforceable and practicable, provided that recommendations for the clarification of certain articles are adopted. The requested clarifications also avoid giving manufacturers room to add distinguishing features to their packaging. These clarifications have been incorporated. This order does not have a significant impact on the practices used by the NVWA. Packaging for cigarettes and roll-your-own tobacco is already being checked for compliance with the requirements thereof. However, these new, detailed requirements for both the inside and outside of the packaging entail an expansion of monitoring tasks. Packaging will have to be checked for a greater number of aspects. The present order is part of

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<sup>13</sup> See also paragraphs 53 and 55 of the preamble to the Tobacco Products Directive.

<sup>14</sup> See the judgment of the CJEU of 26 September 2018, case C-137/17, *Van Gennip*, ECLI:EU:C:2018:771, paragraphs 50 and 51 and the judgment of the CJEU of 4 May 2016, *Phillip Morris Brands and Others*, C-547/14, ECLI:EU:C:2016:325, paragraphs 73-83 and recently confirmed in *Rechtbank Den Haag* 24 July 2019, ECLI:NL:RBDHA:2019:8534, paragraph 4.4.

the amendments made to the Tobacco and Smoking Products Act and the subordinate rules based thereon for the implementation of the National Prevention Agreement. The extra capacity required for the implementation and enforcement of these amendments has been coordinated within the framework of the National Prevention Agreement. The proposal does not give rise to comments in the context of fraud-proofing.

## 8. Impact on regulatory burden

This ministerial order fleshes out the additional requirements for standard cigarettes and roll-your-own tobacco packaging. The present order has no impact on regulatory burden for citizens. The new requirements for standard packaging will lead to an increase in the regulatory burden for manufacturers. Tobacco manufacturers will need to take note of the amended regulations and then make a one-time adjustment to their production process. Costs will also need to be incurred for the conversion and printing equipment. Furthermore, it will be necessary to make adjustments to the software, and this new software will need to be tested. Testing it is also considered to be an impact on the regulatory burden. Due to the influx of new packaging, retailers will pay special attention to purchasing, stock management and sales. Retailers include all sales outlets for tobacco.

Action (one-time)	Who	Time	Costs	Q	Total
Notification fees for new packaging requirements	Manufacturers and importers	4 hours	€45.00 per hour	100	€18 000.00
Conversion of printing equipment for cigarettes and roll-your-own tobacco	Manufacturers	-	-	-	€580 000.00
Software adjustment for cigarettes and roll-your-own tobacco	Manufacturers	40 hours	€45.00 per hour	69 manufacturers	€124 200.00
Software testing for cigarettes and roll-your-own tobacco	Manufacturers	80 hours	€37.00 per hour	69 manufacturers	€204 240.00
Adaptation of purchasing and stock management	Retailers	8 hours	€45.00 per hour	60 000	€21 600 000.00
<b>Total:</b>		132	€172.00 per hour	60 238	€22 004 000.00

As the table above shows, manufacturers are estimated to require around 132 hours in total in order to manufacture neutral packaging. The hourly rate of pay is estimated at €45.00 for the adjustment of software and the adaptation of purchasing and stock management and at €37.00 for software testing for

cigarettes and roll-your-own tobacco. In some cases, no figure is included. In those cases, the action is more of a general one. This is the case, for example, for the conversion of printing equipment. The impacts on regulatory burden apply to manufacturers, importers and retailers. The total costs for the introduction of neutral packaging thus amount to around €24 004 000. Although these costs are not insignificant, any impacts on regulatory burden are inevitable and necessary to achieve a smoke-free generation in which young people and other vulnerable groups are protected from being tempted to smoke or from being exposed to the risks associated with passive smoking.

The order has been submitted to the Dutch Advisory Board on Regulatory Burden (ATR), which provides advice on how to minimise regulatory burdens for companies and citizens. The board notes that the underlying Tobacco and smoking products decree did not opt for a less burdensome alternative as recommended by the ATR at the time. This amendment to the order logically follows from the choice made earlier. The fact that the requirements are workable and the explanatory note establishes a sufficiently clear picture of the regulatory burden means that the operative part for the amendment to the order can therefore read that the order can be adopted.

## **9. Transitional law and entry into force**

These detailed rules will enter into force on 1 July 2020, at the same time as Article 3.4(1) of the decree, as amended.

## **II Article-specific explanatory notes**

### *Article I*

#### *Part A*

Article I amends Article 3.7 of the Tobacco and smoking products order (hereinafter referred to as 'order'). This amendment possibility is based on Article 3.4(1) and (2) (as amended) of the decree. On the basis of this article, additional requirements can be laid down for the part of the package and outer packaging where the general warning, the information message and the combined health warning are rendered that are provided for in Directive 2014/40/EU<sup>15</sup> (hereinafter referred to as 'Tobacco Products Directive'). More specifically, Article 3.4 of the decree contains a basis for laying down detailed rules with regard to cigarettes and roll-your-own tobacco that provide that the packaging of these products may only have a standardised appearance. As already indicated in paragraph 1 of the general part of this explanatory note, these standard requirements are also internationally known as the 'plain packaging' requirements, and they relate inter alia to the permitted colour, font and font size and other indications on the packaging of cigarettes and roll-your-own tobacco.

#### *Relationship between the current and new packaging requirements*

Articles 3.7 and 3.7a of the order in the version in force before the entry into force of this order already contain a number of requirements that are laid down for tobacco product packaging. Article 3.7 only does so with regard to packaging for cigarettes and roll-your-own tobacco. Article 3.7a contains rules with regard to packaging for *all* tobacco products intended for smoking. The requirements in these articles are also known as 'the ban on glitz and glamour' and include, for example, a ban on the use of striking colours on packaging.<sup>16</sup>

Since Article 3.7 already contains rules that only apply to cigarette and roll-your-own tobacco packaging, the present amending order has opted to remove the requirements that apply to cigarette and roll-your-own tobacco under Article 3.7a from article 3.7a and include them in the new Article 3.7 together with the new requirements that apply to such packaging. The combination of existing packaging requirements and new requirements in Article 3.7(3) to (10) of this order gives rise to the requirements laid down for standard packaging for cigarettes and roll-your-own tobacco. The various paragraphs will be discussed in turn below and explained in greater detail wherever necessary.

#### *Article 3.7(1) and (2)*

The packaging requirements from the paragraphs 1 and 2 of Article 3.7 are taken from the Tobacco Products Directive and remain in force. This means that the combined health warning, the general warning and the information remain mandatory on the front and back of the package and outer packaging of cigarettes

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<sup>15</sup> Directive 2014/40/EU of the European Parliament and the Council of 3 April 2014 on the approximation of laws, regulations and administrative provisions of Member States concerning manufacture, presentation and sale of tobacco and tobacco-related products, and repealing Directive 2001/37/EC (OJ L 127, 2014).

<sup>16</sup> Government Gazette 2018, 23779.

and roll-your-own tobacco provided for by the Tobacco Products Directive.<sup>17</sup>

*Article 3.7(3) and (4): fixed and discretionary provisions*

The subparagraphs of paragraph 3 concern the standard packaging requirements for the entire packaging of cigarettes and roll-your-own tobacco. The provisions set out in this paragraph must always be applied to all cigarette or roll-your-own tobacco packaging. These are the fixed provisions. This means that all packaging for cigarettes or roll-your-own tobacco of whatever kind must *always* be continuous, be unprinted on the inside and must not contain transparent parts, which allows you to, for example, see the cigarettes or roll-your-own tobacco within. This of course also applies to the lid of cylindrical roll-your-own tobacco packaging. Furthermore, the packaging must not contain sound effects that are made, for example, when the packaging is opened or closed.

In addition to what packaging must always contain under paragraph 3, paragraph 4(a) to (d) contains additional options that can optionally be added to the packaging. If someone chooses to make use of these options by including foil or foil paper on the inside of the packaging (subparagraphs a and b), enveloping the packaging with cellophane (subparagraph c) or affixing a reclosable adhesive strip on the packaging (subparagraph d), the further requirements laid down in these subparagraphs must also be met.

The conditions listed in paragraph 3 and, if someone chooses to make use of the options offered by paragraph 4, paragraph 4 are exhaustive; only that which has been regulated is permitted. Everything else is forbidden. Some of these requirements speak for themselves, whereas others are worth explaining in greater detail, which will be done below.

*Foil*

The foil that is included to keep the products fresh (Article 3.7(4)(a)) must not be printed on and may only contain two colour combinations, with one side always being white: either the colour white on both sides of this foil or the colour white on the inside and the colour silver on the outside of the foil. The outside of the foil is understood to be the side of the foil that is not in contact with the cigarettes in the packaging.

The foil that is included as part of the inner packaging to ensure an airtight seal (Article 3.7(4)(b)) may only be silver in colour. This includes roll-your-own tobacco packaging that is cylindrical or cuboid.

*Cellophane and cellophane strip*

With regard to the cellophane (Article 3.7(4)(c)) the requirement is that it must be unprinted, uncoloured and transparent. Furthermore, the strip that is included to remove the cellophane (the cellophane strip) may only be transparent or black and not wider than three millimetres. Moreover, the cellophane strip must run in the same reading direction as the text warning on the combined health warning. A cellophane strip that is placed, for example, diagonally around the packaging is therefore not permitted. Finally, the cellophane strip may include a section of not more than fifteen millimetres that indicates where the strip for opening the

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<sup>17</sup> See Article 9 and Article 10 of the Tobacco Products Directive.

packaging begins. This section may be both black in colour and transparent and may therefore be coloured differently than the cellophane strip itself. If the cellophane strip is transparent, the part used to open the packaging is indicated with a black colour and vice versa.

#### *Article 3.7(5) and (6), fixed and discretionary provisions*

The subparagraphs of paragraph 5 concern the standard packaging requirements for the part of the packaging that is not covered by the health warning. The provisions set out in this paragraph must, as is the case in paragraph 3, always be applied to all cigarette or roll-your-own tobacco packaging. These are the fixed provisions. This means that the part of any packaging for cigarettes or roll-your-own tobacco of whatever kind that is not covered by the health warning may *never* contain sound effects, must have the specific colour Pantone 448 C on the outside and must have a matt and uniform finish.

In addition to what packaging must always contain under paragraph 5, paragraph 6(a) to (e) contains additional options that can optionally be added to the packaging. These options from paragraph 6 respectively concern the manner in which the brand name and brand variant (subparagraph a), but also the number of cigarettes or the number of grams of roll-your-own tobacco (subparagraph b), the manufacturer information (subparagraph c), the calibration mark (subparagraph d) and the bar code (subparagraph 3) must be indicated. If someone chooses to make use of the options offered by paragraph 6, the conditions listed in those subparagraphs must be met. As is the case with the conditions in paragraphs 3 and 4, the conditions in paragraph 5 and, if someone chooses to make use of the options offered by paragraph 6, paragraph 6 are exhaustive; only that which has been regulated is permitted. Everything else is thus forbidden. Most of the requirements in paragraph 6 concern fonts, font colours and font sizes and speak for themselves. Some subparagraphs are worth explaining in greater detail, which will successively be done below.

#### *Font*

In the parts of paragraph 6(a)(2°), (b)(1°) and (c)(2°) that refer the permitted font, this font is always Helvetica without formatting variants. This means that the text must not be in bold, italics or underlined, but should instead be included in the standard Helvetica font.

#### *Use of capital letters*

When it comes to the use of capital letters as provided for in paragraph 6(a)(5°), it is only permitted for the first letter of each word of the brand name or brand variant to be capitalised. In the case of an abbreviation (such as the letters DTB as an abbreviation of the fictitious brand name Dutch Tobacco Brand), capitalising the entire abbreviation is permitted.

#### *Indication of contents*

When it comes to the indication of the number of cigarettes as provided for in paragraph 6(b), only the number of cigarettes in figures may be included on the packaging without this number being followed by a word such as 'cigarettes' or 'units'. In the case of a pack of cigarettes with 20 cigarettes in it, only '20' will be included on the packaging. When it comes to indicating the quantity of roll-your-

own tobacco contained in a package, it is indicated in grams. In the case of roll-your-own tobacco packaging of 40 grams, '40 g' is included on the packaging.

#### *Calibration mark*

Under paragraph 6(d), the outside of packaging may include a calibration mark. The calibration mark can be produced in an automated production process and must be as small and inconspicuous as possible on the packaging. The words 'as inconspicuous as possible' are meant to indicate that the calibration mark should not be larger or more conspicuous than necessary.

#### *Exceptions and additions*

Paragraphs 7 to 9 constitute exceptions and additions to certain subparagraphs of paragraph 6.

Paragraphs 7 and 8 concern roll-your-own tobacco packaging in the form of a pouch or a cylinder. Unlike cigarette packaging, which may only be cuboid under the Tobacco Products Directive, roll-your-own tobacco packaging may be cuboid, cylindrical and pouch-shaped. Paragraph 6(a) lays down the rule with regard to cuboid packaging for cigarettes and roll-your-own tobacco that the brand name and brand variant may only be included on the front, top and bottom. Since cylindrical and pouch-shaped roll-your-own tobacco packaging has a different shape than the cuboid shape referred to in paragraph 6(a), paragraphs 7 and 8 lay down other requirements for the place where the brand name and brand variant may be included. Instead of on the front, top and bottom, the brand name and brand variant may, when it comes to cuboid packaging for roll-your-own tobacco, be included not more than once on the front, back and inside of the flap (paragraph 7). In this order, the inside of the flap does not refer to the inside of the packaging. This requirement therefore does not constitute an exception to paragraph 4, which repeatedly states that all permitted elements and indications on the inside of the packaging (paragraph 4(a) to (d)) must be unprinted.

When it comes to cylindrical roll-your-own tobacco packaging, the brand name and brand variant may be included not more than once on the lid, bottom and curved surface of the packaging (paragraph 8(a), (b) and (c)), this curved surface being opposite the part of the packaging where all the manufacturer's name and address details and the bar code are included. With regard to the manufacturer's name and address details and the bar code, it is provided that they may be included not more than once on the lid, the bottom and the curved surface of the cylindrical packaging (also included in paragraph 8(a), (b) and (c)), this curved surface being opposite the part of the packaging where the brand name and brand variant are included. The brand name and brand variant are thereby on one side and the manufacturer's name and address details and the bar code are on the other side of the cylindrical packaging.

In addition to the above, it is worth explaining that the exceptions in the paragraphs 7 and 8 mean that paragraph 6(a)(2°) to (10°), (c)(2°) to (6°) and (e)(2°) to (3°) continue to apply. This means that the subparagraphs that lay down rules for the font, font colour, font size and other permitted symbols when indicating the brand name and brand variant, as well as the manufacturer's name and address details and the bar code, still apply.

As a supplement to paragraph 6(b), paragraph 9 governs the way the content of

the packaging is to be indicated in the case of a carton of cigarettes or packaging containing multiple packs of roll-your-own tobacco. In the case of a carton of cigarettes with six packages of cigarettes each containing 20 cigarettes, the following may be included on the outer packaging to indicate the total weight of the outer packaging: 20x6, without spaces. In the case of six 40-gram roll-your-own tobacco packages in an outer packaging, the following may be included on this outer packaging: 40gx6, without spaces.

#### *Overlapping with Articles 4a and 4h of the Act*

Lastly, paragraph 10 provides that the standard packaging requirements do not stand in the way of the requirements that apply to the unique identification code and the security feature that must be included on packaging from **[PM]** onwards under Articles 4a and 4h of the Tobacco and Smoking Products Act<sup>18</sup>.

#### *Part B*

The present amending order exempts cigarettes and roll-your-own tobacco from Article 3.7a. All rules that apply to cigarette and roll-your-own tobacco packaging are now included in Article 3.7. Therefore, Article 3.7 does not constitute a supplement to Article 3.7a as regards cigarettes and roll-your-own tobacco but instead replaces Article 3.7a as regards cigarettes and roll-your-own tobacco. Article 3.7a exempts cigarettes and roll-your-own tobacco for the sake of comprehensibility and legibility. By including both cigarettes and roll-your-own tobacco in a single article instead of spreading them over multiple articles, it immediately becomes clear which requirements are applicable to cigarette and roll-your-own tobacco packaging.

#### *Part C*

To make it possible to sell the stocks of products that have already been manufactured, the ministerial order includes a transitional provision in Article 7.3(7) in the form of a clearance sale arrangement. This clearance sale arrangement provides that packages or outer packaging of cigarettes and roll-your-own tobacco that were manufactured or released into free circulation before 1 July 2020 and comply with the rules that were in force immediately prior to the amendment to the packaging requirements may still be sold to consumers for one year after 1 July 2020. This period has been fixed at one year because this period was shown to be sufficient in the case of the clearance sale period observed for the introduction of the combined health warning when the Tobacco Products Directive was implemented.

#### *Article II*

It is envisaged to bring into force the amended Articles 3.7(3) to (10), 3.7a(7) and 7.3(7) from 1 July 2020, at the same time as the amended Article 3.4(1) of the decree. From that date, it will only be permitted to manufacture standard packaging for cigarettes and roll-your-own tobacco for the Dutch market.

This order (and the explanatory notes) will be published in the Government Gazette.

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<sup>18</sup> *Parliamentary Papers II* 2018/19, 35 204, Nos 2 and 3.

The State Secretary for Health,  
Welfare and Sport,

Paul Blokhuis