EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

Notification Number : 2021/0427/B (Belgium)

Royal Decree amending the Royal Decree of 28 October 2016 on the manufacture and marketing of electronic cigarettes

Date received : 06/07/2021
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Message

Message 002

Communication from the Commission - TRIS/(2021) 02553
Directive (EU) 2015/1535
Translation of the message 001
Notification: 2021/0427/B

No abre el plazo - Nezahajuje odklady - Fristerne indledes ikke - Kein Fristbeginn - Viivituste perioodi ei avata - Καμμία έναρξη προθεσμίας - Does not open the delays - N'ouvre pas de délais - Non fa decorrere la mora - Neietekmē atlikšanu - Atidėjimai nepradedami - Nem nyitja meg a késéseket - Ma’ jiftaħx il-perijodi ta’ dawmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Määräaika ei ala tästä - Inleder ingen frist - Не се предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 202102553.EN)
1. MSG 002 IND 2021 0427 B EN 06-07-2021 B NOTIF

2. B

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4. 2021/0427/B - C60A

5. Royal Decree amending the Royal Decree of 28 October 2016 on the manufacture and marketing of electronic cigarettes

6. Tobacco products

7. - 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 Text with EEA relevance

8. This draft amends the Royal Decree of 28 October 2016 on the manufacture and marketing of electronic cigarettes, which partially transposes Directive 2014/40/EU.

The proposed amendments are mainly related to adding or updating terms and definitions, and to notification, composition, technical standards, labelling and distance sales. In addition, this draft sets out rules on electronic cigarettes and refill containers without nicotine.

More specifically, with regard to terminology, it adds the terms ‘refill container without nicotine’, ‘importer in Belgium’, ‘health warning’, ‘flavourings’, ‘cross-border distance sales’ and ‘retail outlet’. The term ‘importer of electronic cigarettes and refill containers’ is now amended.
We added the term ‘importer in Belgium’ to have an agent in Belgium, so the inspection service can take measures against non-compliant companies. The definition of importer actually does not allow for the prosecution of non-compliant importers or manufacturers. Since the RD came into force, numerous companies have been in breach and under the current definition, the inspection service cannot take any action against them. This addition is strictly necessary and essential to public health. Because some Member States do not have a monitoring body (e.g. France), Belgium has a duty to take its own measures to safeguard the health of its citizens and ensure application of the Directive in full.

The draft amends Article 3 of the Royal Decree with regard to notification, in particular for the final responsibility for the notification procedure, the data to be submitted, publication of a positive list on the website of the Service, fee payment and an annual fee for data processing.

The draft rewrites Article 4 of the Royal Decree, on composition and technical standards, to apply several amendments: the ban on disposable cigarettes, the ban on attractive features not useful to e-cigarette functioning, the option for the Minister for Public Health to adopt a list of prohibited and/or approved additives in electronic cigarettes and refill containers and the requirement for child safety devices to meet standard ISO 8317:2003.

The draft also rewrites Article 5 of the Decree to distinguish the provisions applicable to the health warning from those applicable to the text of this warning.
Moreover, it clearly states that the leaflet and list must be available in at least the three national languages. The draft then adds that the list must include the product ID issued by the EU-CEG notification system. It further sets a requirement for refill containers to bear an expiry date.Finally, it clarifies that the brand and sub-brand appearing on the product packaging must be the same as those entered in the EU-CEG notification system.

Article 6 of the Decree is now amended to ban the distance purchasing of e-cigarettes and refill containers. Further, the draft adds that cross-border distance sales are permitted if allowed under the legislation of the Member State of destination.

It now adds Article 6/1 to make certain provisions of the Royal Decree applicable to refill containers without nicotine. In addition, it also provides for a special health warning for these products. Finally, the draft states that refill containers cannot exceed a volume of 60 millilitres.

The draft amends Article 7 of the Decree to add that the manufacturer, importer, importer in Belgium and retail outlet may be held liable for breaches of the Decree.

9. With regard to terminology, addition of the term ‘refill containers without nicotine’ is necessary so the provisions of the Royal Decree apply to these products.
Addition of the term ‘importer in Belgium’ is intended to increase the capacity of the inspection service to act in response to breaches.

The draft adds the terms ‘health warning’, ‘flavourings’, ‘retail outlets’ and ‘cross-border distance sales’ because they were missing (provided in Directive 2014/40 but not in the Decree).

With regard to notification, the draft applies a number of changes. With the new terms and definitions, it is now possible to make the importer in Belgium responsible for this procedure. In practice, the producer or importer in the EU may submit the notification details, even if neither of these undertakings has a registered office in Belgium. However, it is the importer in Belgium that is responsible for this. This means any penalties for infringements can be imposed on an undertaking whose registered office is located in Belgium.
The notification file must also be supplemented with the labelling of the packaging units placed on the market and the leaflet referred to in Article 5(§ 9). This reinforces the tools available to inspectors and give authorities a better overview of the quality of the information provided in this leaflet.
Any and all product modifications must result in corresponding changes to the notification file submitted to the Service so the files are in accordance with the products placed on the market. All changes applied in a file are considered substantive changes. The only exceptions are: changes requested by the Service, changes in contact information and the addition of sales volume figures for the preceding year.
Finally, the draft also applies changes related to fees. It introduces three different fees, according to the associated administrative burden.
A fee of EUR 200 applies to new product registration.
Changes to existing product registrations incur a fee of EUR 100.
Each product registered is subject to an annual fee of EUR 50 to cover the costs of processing the data to be submitted each year. In addition, the draft now states that the notifying party must provide these annual data before 1 March of the following year.
The amendment to the Decree also allows incorporation of the principle of listing the products with complete notification files on the website of the Service (on a ‘positive list’).
For a product to appear on the positive list, the notifying party must enter the data as requested by the Service. This is vital so data can be compared between different files. In cases of failure to follow these instructions and make requested corrections, the products will not appear on the positive list. The same applies in cases of failure to pay the fee.
Products not appearing on this list cannot be placed on the market and must be considered harmful, and are therefore subject to the criminal penalties provided for under this Decree. It is therefore the responsibility of vendors to check that the products they sell are on this public list. In practice, this means that the notifying party must amend the notification file as requested by the Service.

As for composition and technical standards, disposable electronic cigarettes are now banned because the Superior Health Council of Belgium [Conseil Supérieur de la Santé], in its opinion of 2015, recommended not approving disposable electronic cigarettes due to their environmental impact and encouragement of tobacco consumption. The Superior Health Council further stated: ‘the same applies to very cheap disposable e-cigarettes, which are clearly placed on the market to encourage people of less financial means to try them, as was formerly the case with packs of 10 tobacco cigarettes. It is clear that the intention is to make the step towards tobacco consumption/vaping as easy as possible, in order to transition towards higher consumption and possibly also tobacco consumption.’; and ‘disposable e-cigarettes that are flavoured or feature gadgets (lights, coloured smoke, etc.) pose a risk of renormalising smoking and attracting a non-smoking public.’
In addition, this draft also bans placement on the market of electronic cigarettes with attractive features that are not useful to the functioning of the device. In particular, this covers the SHC recommendations in opinion 9265 of October 2015, stipulating that ‘e-cigarettes (…) fitted with gadgets (…) (lights, coloured smoke, etc.) must be regulated, controlled and banned.’. This means electronic cigarettes cannot have any function other than the production of vapour to be inhaled.Videos of devices that use an LED lamp to change the vapour colour are available on the internet and social networks. Some try to make the vapour into shapes, for instance. Electronic cigarettes must not be used for this purpose. An electronic cigarette is and remains a product that must not be presented in an attractive manner.
The option granted to the Minister to adopt a prohibited additives list and/or an approved additives list is intended to facilitate the banning of certain additives shown to be harmful (such as THC).
The requirement for child safety devices to meet standard ISO 8317:2003 is intended to make them safer.
The requirement for refill containers to bear an expiry date is intended to protect consumers. The Inspection Service of

the Federal Public Service for Public Health has found refill containers with lapsed expiry dates on the Belgian market, which is not currently prohibited even though use of expired liquid may affect consumer health.

The amendments to Article 5 (labelling) with regard to the health warning and the text of the warning are intended to improve clarity.
With regard to the leaflet, it was necessary to specify that it must be available in all three national languages, because this obligation was not clear.
The draft adds the requirement for the list to contain the product ID provided by the EU-CEG system, to facilitate product control and make it easy for vendors/importers to tell whether or not a product has been notified.
It makes a clarification regarding the brand and sub-brand appearing on the packaging, which must be identical to those in the EU-CEG system.

For the sake clarity, along with the ban on distance sales, the draft also bans distance purchasing. Further, it adds that cross-border distance sales are permitted if allowed under the legislation of the Member State of destination.

New Article 6/1 is intended to set obligations on e-liquids without nicotine.
It was necessary to regulate these previously unregulated products because they are also harmful to health. The Superior Health Council of Belgium also recommended certain rules in its opinion of 2015. It states: 'The SHC recommends that the quality requirements on e-cigarettes with nicotine be identical to those without nicotine (apart from with regard to the nicotine).'
Here, wherever possible the draft refers to the requirements applicable to electronic cigarettes and refill containers with nicotine, in accordance with Directive 2014/40/EU.

The amendment to Article 7 is intended to make manufacturers, importers and retailers responsible for breaches of the Decree.

10. References to basic text(s): The Royal Decree of 28 October 2016 on the manufacture and marketing of electronic cigarettes

11. No

12. -

13. No

14. No

15. -

16. TBT aspect

NO – The draft does not have a significant impact on international trade.

SPS aspect

NO – The draft does not have a significant impact on international trade.

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European Commission

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