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

Notification Number : 2023/0215/B (Belgium)

Royal Decree of XXX on the manufacture and placing on the market of tobacco products and herbal smoking products

Date received : 25/04/2023
End of Standstill : 26/07/2023 (26/10/2023) (closed)

Message

Message 002

Communication from the Commission - TRIS/(2023) 01154
Directive (EU) 2015/1535
Translation of the message 001
Notification: 2023/0215/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: 202301154.EN)
1. MSG 002 IND 2023 0215 B EN 25-04-2023 B NOTIF

2. B

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4. 2023/0215/B - X00M

5. Royal Decree of XXX on the manufacture and placing on the market of tobacco products and herbal smoking products

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. The purpose of this draft Royal Decree is to rewrite the Royal Decree of 5 February 2016 on the manufacture and placing on the market of tobacco products and herbal smoking products in order to:
- transpose the Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions for heated tobacco products,
- making it clearer and more legible

9. There is a significant change in definitions. A definition of the word “product” has been added to include tobacco products and herbal smoking products.
This simplifies the reading of the Decree, as many provisions apply to both categories.
Similarly, the definition of a device falling within the scope of the Decree is expanded to include devices for all products. Until now, only devices for new tobacco products have been covered by this definition. Therefore, all devices with which a tobacco product (e.g. waterpipe) or a herbal smoking product (e.g. vaporiser) can be consumed are subject to the corresponding provisions (including notification, labelling rules, distance selling ban)

A definition of heated tobacco product is also added, based on the definition of the Delegated Directive 2022/2100. According to this Delegated Directive this new category of new products must comply with stricter labelling requirements. With respect to other new tobacco products, the old rules still apply, i.e. the Minister will determine which of the provisions of Articles 8, 9 and 10 will apply to them.
Heated products not containing tobacco but other plant substances will also be subject to the provisions applicable to herbal smoking products.

Article 4 on the notification has been completed. First, the notification of all products, namely (new) tobacco products and herbal smoking products, is included in this Article. The product notification must now also include the name and contact details of the manufacturer, importer and, where applicable, of the importer in Belgium. Furthermore, additional information is required for new tobacco products. The decree also provides for mandatory notification of devices to be placed on the Belgian market, except for pipes and waterpipes. For devices, various data must be communicated to the department, including a description of components, directions for use, a fact sheet, etc.
As regards the notification of devices, it should be clarified that in the EUCEG system this is only possible for devices intended for new tobacco products. The notification obligation therefore currently only applies to these devices. However, with the extension of the definition, as soon as the system allows and subject to timely communication by the Department, we will apply this obligation to the devices of all other products.

An importer whose registered office is located in another Member State may also submit the notification.

There are also other changes to the notification procedure:
- Notification for tobacco products will no longer be required annually.
- It is legally specified that the Department may request to complete the information submitted. Additional testing may also be required for new tobacco products.
- The new Decree explicitly states that the products will only be placed in the positive list on the FPS website if the information submitted is complete and the royalty has been paid to the Reporting Service. Products and devices not included in the list of validated products and devices shall not be placed on the market.

The Decree sets new royalty prices for the notification procedure:
- EUR 200 for tobacco products and herbal smoking products,
- EUR 4,000 for new tobacco products and devices.

Substantial changes require an update of the file and the payment of an additional royalty of EUR 100 per product or device.

Each year, additional data must be entered in the file, including studies, sales volume figures, etc. An additional royalty of EUR 50 per product or device is required for this purpose.

Finally, it is legally specified that royalties are due as soon as data are entered into the system and are payable to the Budgetary Funds within 30 days of sending the invoice. Fees are not recoverable in any way.

The former Article 5 on composition becomes Article 6 and is reinforced. Thus, compositional requirements become stricter for new tobacco products and herbal smoking products. For example, they may not have filters, paper and capsules that contain tobacco and/or nicotine.
As regards the ban on the placing on the market of technical elements which could alter or improve the smell, taste, intensity of combustion, smoke production, colour of emissions and/or consumption of products, we would like to give some examples of products concerned: instant pellets inserted in filters that change the taste of tobacco, flavoured leaves for rolling tobacco, etc.

Labelling requirements are also strengthened. Thus, Article 7 provides that health warnings of new products may no longer be affixed by means of adhesives.

The provisions of the former Article 9 of the Royal Decree are deleted so that the rules on the labelling of tobacco products for smoking are the same for all these products. The Article is complemented by the provisions on combined health warnings for tobacco products. Cigars and cigarillos that were previously exempt from certain labelling requirements will now be labelled like other tobacco products for smoking (cigarettes, rolling tobacco and waterpipe tobacco). They will therefore have the combined health warning and the information message.

The provisions on new tobacco products transpose Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions for heated tobacco products. These provisions go further than the Delegated Directive, because new heated tobacco products are considered to be tobacco products for smoking because similar harmful substances are inhaled when the product is used. This implies that these products must be labelled as tobacco products for smoking (combined health warnings and information message).

The prohibition on the offer of products is added to the prohibition on distance selling and buying of Article 14. This prohibition is interpreted by analogy with the prohibition on the offer of alcohol and tobacco products to minors. Products and devices simply cannot be made available to Belgian consumers online. This means that websites/platforms must be secure in order to ensure that Belgian consumers simply cannot buy these products and devices.

In the Royal Decree of 5 February 2016, it was stated that the provisions of Article 14 applied to devices (new tobacco products). Therefore, a new tobacco product device had to carry the health warning for smoking or smoke-free tobacco products (according to the Minister’s decision). Since a device does not contain tobacco in itself, a specific warning is

provided on the packaging. By analogy, this warning is also provided for all other devices enabling the consumption of tobacco products or herbal smoking products. The aim is to warn consumers that the consumption of products using these devices is harmful to health. These products are very similar to conventional products and have a similar effect, so a warning is necessary.

The issue of liability for infringements is linked to the concept of “placing on the market”. This concept refers to the mere intention of making products available to consumers in the Union and not to the actual making available of the products to consumers (i.e. when they are available for sale). This has been confirmed by the European Commission by email to the Inspection Service on 14.8.2019. This position was confirmed again by the Commission at the meeting on 15.10.2019. The Commission states in its meeting report:
“ One Member State raised a discussion point on the concept of “placing on the market”, primarily in relation to inspections and enforcement activities. SANTE recalled that several provisions of the TPD referred to the intended destination market. In addition, the TPD contains provisions with obligations and requirements that already apply at the manufacturing or distribution stage, and as such, prior to the placing on the market (e.g. TNCO levels, traceability). Finally, it should be considered that, in principle, the actual destination market must be defined at the time of packaging, given its regulatory relevance with regard to TPD requirements (i.e. type of combined health warnings, traceability markings, and fiscal markings/security features).”
The presence on products of health warnings in the 3 national languages is a factor (sufficient) to consider that the product is placed on the Belgian market, regardless of where it is stored along the logistics chain.

Note that this motivation must be read in conjunction with the motivation of the TRIS notification 2018/446/B which is still valid for this project.

10. References to basic texts: Royal Decree of 5 February 2016 on the manufacture and placing on the market of tobacco products and herbal smoking products
The reference texts should be sent as part of the previous notification: 2018/446/B

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

Contact point Directive (EU) 2015/1535

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