Work Package 7

D 7.1

Report on regulation of novel tobacco products and e-cigarettes in different EU MS

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Introduction

In 2001, the European Union (EU) adopted the Directive 2001/37/EC on manufacture, presentation and sale of tobacco products in the EU. Due to considerable developments in new scientific evidence, for example on tobacco flavourings and effectiveness of health warnings, and also appearance of new products, such as electronic cigarettes (hereafter e-cigarettes) and flavoured tobacco products on the market, the Council and the European Parliament requested a revision of the Directive 2001/37/EC. In April 2014, the EU completed the first revision of this directive, repealed and replaced the Directive 2001/37/EC with the Directive 2014/40/EU[1] (hereafter TPD). The TPD entered into force on 19 May 2014 and became applicable in the EU Member States on 20 May 2016.

The TPD aims to reduce the differences in approaches to tobacco regulation in the 28 EU Member States, laying down minimum rules for cigarettes, cigars, pipe tobacco, waterpipe tobacco, cigars and cigarillos, smokeless tobacco, roll-your-own tobacco and e-cigarettes. However, differences in implementation of the TPD, as well as additional Member State-specific regulations have resulted in differences in tobacco product regulation between the Member States. To cover a wide range of differentiated products, the TPD broadly defines this category (e-cigarettes) to include not only the device and its parts but also the refill containers with nicotine containing e-liquid.

The TPD provisions for "novel tobacco products" were designed to provide a wide regulatory net for new tobacco products that rapidly enter the EU market. As can be expected with such a wide product range, it cannot cover product specific properties at the level of detail that may be needed for effective regulation. As such, the date-based definition[2] is too general to cover product specific aspects, like claims on ingredients. Recently, new products have been developed that are used as or with tobacco products, such as nicotine pouches or flavouring accessories, which do not contain tobacco themselves and are therefore not regulated in the TPD. As such products are not in support of tobacco control policies, regulators may wish to discourage their use and thus additional regulation may be needed. Moreover, the implementation of TPD provisions regarding novel tobacco products depends on

[1] DIRECTIVE 2014/40/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL 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

[2] The TPD defines this category as tobacco products placed on the market after 19 May 2014, which do not fall into any other product category (i.e. cigarettes, RYO tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use) under the Directive.

whether these products are defined as smokeless tobacco products or tobacco products for smoking (Article 19, paragraph 4) which is important as categorization affects rules and regulations that need to be followed. Therefore, the EU regulatory framework currently neither covers all novel tobacco products, nor provides flexibility to address rapid product developments. In some cases, this has led to country specific regulation of products that fall within or outside of the scope of "novel tobacco products".

The aim of this report is to provide an overview of the information on Member States' specific legislation for novel tobacco products, e-cigarettes and related products that fall outside the scope of novel tobacco products (herbal products for smoking are not included in this overview). The report is the deliverable of the Joint Action on Tobacco Control 2 (JATC2, 2021-2024, D7.1) linked to the Work Package 7, Task 7.1b. The general objective of the JATC2 is to provide support for the implementation of the TPD throughout the Member States, while the aim of Task 7.1b is to investigate differences in regulation of novel tobacco products, e-cigarettes and other products across Member States. In Task 7.1a EU-CEG data will be analysed to create an overview of novel tobacco and e-cigarette products that were submitted to be marketed in the different Member States In this task (7.1b) additional information was obtained, from other sources than EU-CEG (in task 7.1a) to provide a more complete overview of the tobacco related products on the market, but not submitted to EU-CEG, and on related national regulatory efforts.

In this deliverable, the definition of e-cigarettes, novel tobacco products and other products include the following:

- nicotine-free and nicotine-containing e-liquids, vaping devices and CBD products,
- novel tobacco products and associated devices (i.e. heated tobacco products (hereafter HTP)),
- novel products that may not fall under the TPD scope, such as nicotine pouches and flavour cards.

In order to investigate the regulation of novel tobacco products and e-cigarettes between EU Member States, a questionnaire was prepared and shared with contact persons from EU Member States and Norway. The questionnaire included three thematic sections - *E-cigarettes and refill containers*, *Novel tobacco products* and *Other* with 47 questions, see *Appendix/questionnaire*. All definitions in the questionnaire are stated in the Article 2 of the TPD. This report is based on answers from the twenty-three Member States, including Norway that has not implemented the TPD yet.

Data collection

Information was collected by using a questionnaire, which was sent electronically to all EU Member States' and Norway public health authorities in order to investigate

differences in regulation of novel tobacco products, e-cigarettes and other products. Twenty-five Member States and Norway responded the questionnaire. Note that Norway has not implemented the TPD, which means that they may have chosen a different approach than the other countries.

Croatia	HR	Germany	DE	Lithuania	LT	Norway	NO
Slovakia	SK	France	FR	Austria	AT	Greece	GR
Netherlands	NL	Cyprus	CY	Belgium	BE	Sweden	SE
Slovenia	SI	Latvia	LV	Czech Republic	CZ	Estonia	EE
Bulgaria	BG	Poland	PL	Spain	ES	Portugal	PT
Finland	FI	Denmark	DK	Italy	IT	Hungary	HU
Malta	MT	Ireland	IE				

Providing information on the product

All Member States require novel tobacco products, e-cigarettes and refill containers to be reported to the EU Common Entry System (EU-CEG) before entering the market, as outlined in the EU TPD. However, some Member States require approval of products before they can enter the market, whereas other Member States exercise a notification procedure. According to the TPD, manufacturers and importers must submit their notifications at least six months before they intend to place a product on the market. This allows the Member States time to review the notification. Some Member States do not apply the full six months period or approve the notification of products before that period is over.

Confirmation or approval of products

Sixteen Member States (26/16: HR, SK, HL, AT, LT, CZ, SE, EE, DE, FR, CY, LV, PL, MT, PT, IE) neither approve nor confirm when they receive notifications of e-cigarettes and refill containers. Nine Member States (26/9: SL, BG, FI, BE, IT, ES, DK, GR, HU) reported that they practice confirmation procedure. Four Member States (26/4: SL, BE, ES, HU) approve e-cigarettes before they can enter national market. In addition, some Member States commented on how they confirm received notifications of e-cigarettes: in France an automatic receipt for each submission by the EU-CEG system is generated, Latvia sends confirmation along with the payment instructions, Poland and Malta reported that submitters are contacted only if there are deficiencies in the submissions. The TPD has not entered into force in Norway, when it is set into force, Norway will (the Medicines Agency) either decline or approve the notification. It will not be allowed to sell electronic cigarettes before a submitter receive a written approval from the agency.

Regarding novel tobacco products, eleven Member States (26/11: HR, NL, CZ, SE, EE, DE, FR, CY, LV, LT, EI) neither confirm nor approve the receipt of notifications of novel tobacco products. Eleven Member States (26/11: SL, SK, FI, BE, ES, IT, PT, PL, DK, GR, HU) reported that they confirm received notifications of novel

tobacco products. Eight Member States (26/8: BG, AT, BE, ES, PT, PL, HU, NO) responded that they approve the notification of novel tobacco product before the product can enter their national market.

Several Member States commented on how they approve or confirm novel tobacco products. In Germany, manufacturers and importers of novel tobacco products additionally need to apply for authorization after submitting notification through the EU-CEG. Belgium mentioned that they confirm received notifications for novel tobacco products, but have not approved any such products yet. In Czech Republic placing of a new tobacco product on the market is not approved and responsibility for compliance with all legal requirements lies with the submitter. Estonia confirms reception of the notification on their web site.

Norway has, for approval of novel tobacco- and nicotine products, an authorization scheme with similar requirements as in the article 19 of the TPD. In addition, there is an extra requirement stating that in processing the application, the Norwegian Directorate of Health must place particular emphasis on whether the product can be attractive to children and young people or contribute to the initiation or normalization of tobacco use. More information, including the compilation of notification procedures between the Member States, can be found in *Table 1*.

Member State	E-cigarettes and refill containers			Novel tobacco products		
	Confirm	Approve	Neither confirm nor approve	Confirm	Approve	Neither confirm nor approve
Croatia			x			x
Slovakia			x	x		
Netherlands			x			x
Slovenia	x	x		x		
Bulgaria	x				x	
Finland	x			x		
Lithuania			x			x
Austria			x		x	
Belgium	x	x		x	x	
Czech Republic			x			x
Spain	x	x		x	x	
Italy	x			x		
Sweden			x			x
Estonia			x			x
Portugal			x	x	x	
Germany			x			x
France			x			x
Cyprus			x			x
Latvia			x			x

Poland			x	x	x	
Denmark	x			x		
Ireland			x			x
Greece	x			x		
Hungary	x	x		x	x	
Malta			x			
Norway					x	

Table 1

The majority of the Member States (23/26) reported that both manufacturers and importers are obliged to notify novel tobacco products, e-cigarettes and refill containers, see *figure 1*. Portugal and France reported that they require submission of novel tobacco products and e-cigarettes from either manufacturer or importer. Poland commented that e-cigarettes shall be notified either manufacture or importer, but only manufacturers are obliged to notify novel tobacco products. In Ireland, if the manufacturer has not notified a product the importer must.

Launching products on the market

The majority of the Member States do not allow manufacturers and importers to launch novel tobacco products, e-cigarettes and refill containers sooner than six months prior placing on the market, see *Figure 1*.

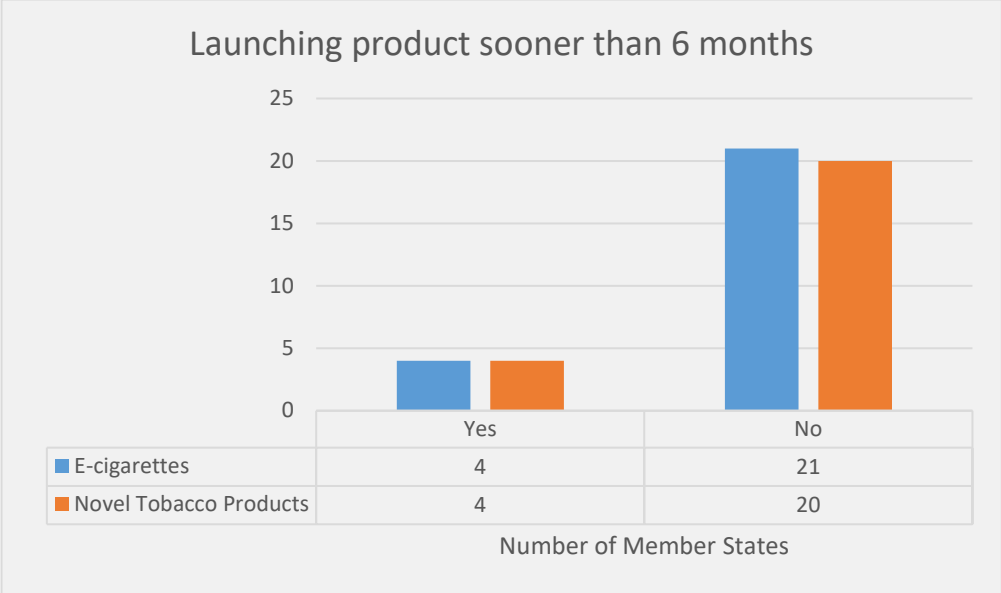

Figure 1

However, some Member States exercise a procedure that allow manufacturers and importers to launch products on the market faster than six months after the first submission date, usually when the payment for the submitted notification is received and information about the submitted product is made publicly available on the responsible authority's web site, see *table 2*.

Member States that allow to launch products sooner than 6 months	
E-cigarettes & refill containers	Novel tobacco products
Belgium	Czech Republic
Slovenia	Slovenia
Spain	Spain
Denmark	Germany

Table 2

Slovenia and Spain do not apply the full six months period and allow launching both e-cigarettes and novel tobacco products before the end of the 6-month period. In Slovenia, the products can be launched after the payment is received.

Spain allows faster launching process of e-cigarettes, usually after reviewing submitted information and positive communication with the submitter. Novel tobacco products can be placed on the Spanish market after the approval of the notification.

In Belgium it is possible to launch e-cigarettes and refill containers faster than six months on the conditions that the product complies with the requirements, validated by the data manager and the fee for the product notification has been paid. Only after that, the information on this product will be published on the authority's web site in a "positive list".

Denmark allows also faster launching of e-cigarette products when payment is received and when the products are registered on the public list of registered products.

In Germany novel tobacco products can be placed on the market as soon as they are authorized by the competent authority, the authorization process depending on the case can take between 3 and 9 months.

Czech Republic reported that in general novel tobacco products have to be notified six months prior intended placing on the market. However, there have been cases of submissions on previously submitted novel tobacco products of the type "Substantial modification of information on a previously reported product leading to a new Product ID" when the period before launching was shorter than six months.

Notified novel tobacco products

Almost all Member States, provided brand names of heated novel tobacco products submitted for their national markets, see *table 3*. Information from Portugal is missing, since brand names are considered confidential.

Member States	Heated tobacco products
Slovakia	IQOS
Netherlands	Stieck, Nuso, Neo, Heets, Terea, MC, Marskiss
Slovenia	NEO, NIT, NUSO, DARLINGS, HEETS, MC
Bulgaria	HEETS, FIIT, DUNHILL
Finland	NEO, MARKISS, Stieck, Nuso, MC
Lithuania	HEETS, TEREA, NEO, DARLINGS, COO, NIT, NUSO, MC
Austria	Heets (PM), Neo-Sticks (BAT)
Belgium	Heets, STIECK, LEME, MC
Czech Republic	Heets, IQOS, COO, MOK, Neo, Glo, MC, My Choice, iD, Pulze, NUSO, ISMOD, Heccig (identical with NUSO), Fiit, lil SOLID, Camel sticks, Ploom New notifications: Darlings, NIT, CTOM, STIECK
Spain	Heet Sticks, Glo, Neo sticks, Stieck, Terea, Fiit, NUSO, MC COO, Kuanzai, MARKISS, IQOS
Italy	Heets sticks, Neo Sticks, Terea sticks, Camel Sticks, Nuso, COO, Fiit, Marskiss, Idcapsule
Sweden	MC, Marskiss, Heets, Nuso
Estonia	Heat sticks
Germany	Heet Sticks, Glo, Neo sticks, Stieck, Terea, Fiit, NUSO, MC COO, Kuanzai, MARKISS
France	Heets, Neo sticks
Cyprus	Heet Sticks, Neo, Nuso, MC
Latvia	Heet Sticks HEETS/IQOS, MC, TEREA, Nuso, STIECK, NIT, Fiit, BLK and manufacturer classify as smokeless tobacco products.
Poland	MARLBORO HEAT STICKS, IQOS, NEO STICKS, GLO, CAMEL TECH – CAPS and PLOOM TECH, Camel STICKS and PLOOM, FIIT (sticks), IiI SOLID, MC (sticks), My Choice
Denmark	HEETS STICKS, NEO
Norway	IQOS, GLO
Croatia	IQOS HHEATS by PMI, NEO STICKS by BAT, DARLINGS, NUSO, NIT
Greece	TEREA, Heets, NEO, STIECK, MC, NUSO, FIIT, NIT, ID, BLK, GS
Portugal	Brand names are considered confidential
Hungary	neoTM Bright Tobacco, neoTM Golden Tobacco, neoTM Green Click, neoTM Afternoon Daydream, neoTM Sunrise Twist, neoTM Sunset Swing, neoTM Tropic Click, neoTM Purple Click, neoTM Scarlet Click, neoTM Blue Click, neoTM Terracotta Tobacco, neoTM Beryl Mix, TM Purple Mix, EHTP (HEETS Abora Pearl, HEETS Amarelo Fuse, HEETS Amelia Pearl, HEETS Gold Selection, HEETS Lilac Fuse, HEETS Ruby Fuse és HEETS Satin Fuse, TEREA Amber, TEREA Blue, TEREA Bronze, TEREA Mauve Wave, TEREA Russet, TEREA Sienna, TEREA Silver, TEREA Teak, TEREA Turquoise, TEREA Yellow, TEREA Willow, TEREA ABORA PEARL, TEREA AMELIA PEARL, TEREA BRIZA PEARL, TEREA DIMENSIONS APRICITY, TEREA DIMENSIONS YUGEN, TEREA LAGUNA SWIFT, TEREA RUBY FUSE, MC Brown, MC Orange, iD Balanced Blue, iD Ice, iD Polar Green, iD Rich Bronze, iD Capsule Forest Purple, iD Capsule Polar Green és iD Capsule Summer Red, HEETS Sienna Caps, HEETS Mauwe Wawe, Fiit Marina és Fiit Regular, Fiit Regular Deep és Fiit Roxo, Coral Tide, Dimensions Ammil, Dimensions Apricity, Dimensions Noor, Dimensions Yugen ,Laguna Swift, Fiit Regular Sky, Fiit Island, Fiit Spring, MC Green Intense, MC Red, MC Bluemerry, és MC Gold, NUSO Brown/Blue/Yellow/Purple/Lawn/Green/Ice-storm, neoTM Sunset Swing, neoTM Midnight Sun, neoTM Twilight Dance, neoTM Sunset Swing, neoTM Midnight Sun, neoTM Twilight Dance, EHTP Teak Selection, EHTP „Silver Selection", EHTP „Russet Selection"
Ireland	No information on novel tobacco products was provided

Member States	Heated tobacco products
Malta	No information on novel tobacco products was provided

Table 3

In addition to the abovementioned heated tobacco products, several Member States provided information on other types of novel tobacco products that have been notified through the EU-CEG for their national markets. Norway reported applications for authorization on several nicotine products.

The Netherlands noted several heated herbal products CCOBATO, UNICCO, GENMIST, DARLINGS and NEAFS.

Croatia shared information on several other novel tobacco products emerging on their market, such as STICKS HIBISCUS RT MINT, STICKS SMOOTH, STICKS CITRIC, STICKS BRIGHTS, STICKS RICH, STICKS DARK FRSH HIGH NIC, STICKS FRESH MIX LOW NIC, STICKS BOOST, STICK ROASTED TOBACCO.

Czech Republic reported on the following novel tobacco products that have been notified: DREAM STEAM STONES (limestones with aroma without tobacco for use in shisha), several devices for use of heated tobacco product such as HITASTE, GS and BLK, THERMALOUCIUOC (dry herb vaporizer, device only).

Belgium mentioned even heated herbal products, notified as herbal products: Ccobato, Neafs.

Twenty-one Member States (21/26: BE, CZ, AT, LT, FI, BG, NO, SI, CR, IT, EE, PT, FR, CY, LV, ES, DE, PL, DK, GR, HU) reported that they require completions of notifications due to incorrect and/or incomplete submission of novel tobacco products.

Eight Member States (8/26: BE, CZ, AT, PT, ES, DE, PL, HU) indicated that they requested additional information on tests of specific novel tobacco products from manufacturers and importers for the following novel tobacco products: IQOS, HEETS, COO, MC, NUSO, HECCIG, DARLINGS, NIT, CTOM, GLO, KUANZAI, MARKISS, CAMEL STICKS and FIIT.

Banning of ingredients and flavours

Member States take different approaches in regulation of the ingredients, additives and flavours in novel tobacco products, e-cigarettes and refill containers. While some Member States allow the tobacco industry to use certain ingredients, additives and flavours, other Member States prohibit the use of these ingredients. As a result, some ingredients are regulated in certain Member States, but not in others.

Member States were asked whether they ban flavours in nicotine-containing liquids. Estonia banned menthol as a substance in nicotine-containing e-cigarettes. Denmark recently banned all flavours except menthol and tobacco. Norway has currently a ban on selling nicotine-containing e-cigarettes. Lithuania and Finland ban all flavours except tobacco. Hungary bans all flavours. Four Member States (26/4: NL, ES, SL, LV) are planning to ban flavours in e-liquids in the near future, see *Table 4*.

Flavour ban in e-liquids		
No ban	Planning to ban	Already banned
Belgium	Netherlands	Austria*
Czech Republic	Spain	Lithuania (all flavours except tobacco)
Bulgaria	Latvia	Finland (all flavours except tobacco)
Slovenia	Slovakia	Norway (ban on selling of e-cigarettes)
Netherlands		Estonia (menthol)
Slovakia		Denmark (all flavours except tobacco and menthol)
Croatia		Hungary (all flavours)
Sweden*		
Italy		
Portugal		
France		
Cyprus		
Germany*		
Poland		
Malta		
Ireland		
Greece		
Latvia		
Spain		

Table 4

*Austria reported that they allow nicotine-containing liquids that do not contain additives listed in Art 7 (6) TPD II. Germany mentioned that they don't have flavour ban but the following ingredients/flavourings 2,3-butanedione, 2,3-pentanedione, 2,3-hexanedione, 2,3-heptanedione and coumarin are banned because they pose a risk to human health in heated or unheated form. Sweden reported that Swedish Parliament said no to ban all flavours with exception of tobacco this summer.

Member States were asked if they prohibit any other ingredients in e-cigarettes and refill containers. Germany provided a list of prohibited additives/flavours/ substances that:

- create the impression that the consumption of e-cigarette has a health benefit or poses lower health risks,
- are associated with energy and vitality,

- have colouring properties for emissions,
- have CMR properties in unburned form,
- in heated or unheated form, pose a risk to human health.

Member States also provided information on prohibited ingredients in novel tobacco products, see detailed list of prohibited ingredients in Germany under Appendix section. Austria mentioned prohibition of Titanium Dioxide. Belgium reported prohibition of additives that can facilitate inhalation in novel tobacco products such as menthol and geraniol.

Twenty Member States (20/26: BE, CZ, NL, IT, EE, PT, PL, DE, LT, LT, DK, AT, SE, LV, HU, MT, ES, IE, FR, IT) reported that their national regulations forbid the ingredients mentioned in the article 7 (6) TPD:

- vitamins or other additives that create the impression that a tobacco product has a health benefit or presents reduced health risks;
- caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality;
- additives having colouring properties for emissions;
- for tobacco products for smoking, additives that facilitate inhalation or nicotine uptake; and
- additives that have CMR properties in unburnt form.

Non-nicotine containing liquids

Non-nicotine containing liquids are not regulated by the TPD, which is why Member States do not have a harmonized approach on non-nicotine containing products. Some Member States apply similar provisions on non-nicotine containing products as for nicotine-containing ones, where others do not regulate non-nicotine products.

There are substantial differences between the Member States regarding regulation of flavours in non-nicotine containing liquids. Twelve Member States (12/26: CZ, AT, FI, NL, HR, IT, EE, FR, LV, DE, DK, HU) reported that non-nicotine containing liquids are regulated, six of these Member States (6/26: CZ, FI, NL, EE, DE, DK) pointed out that they applied similar provisions for these liquids as for nicotine-containing liquids, see *figure 2*.

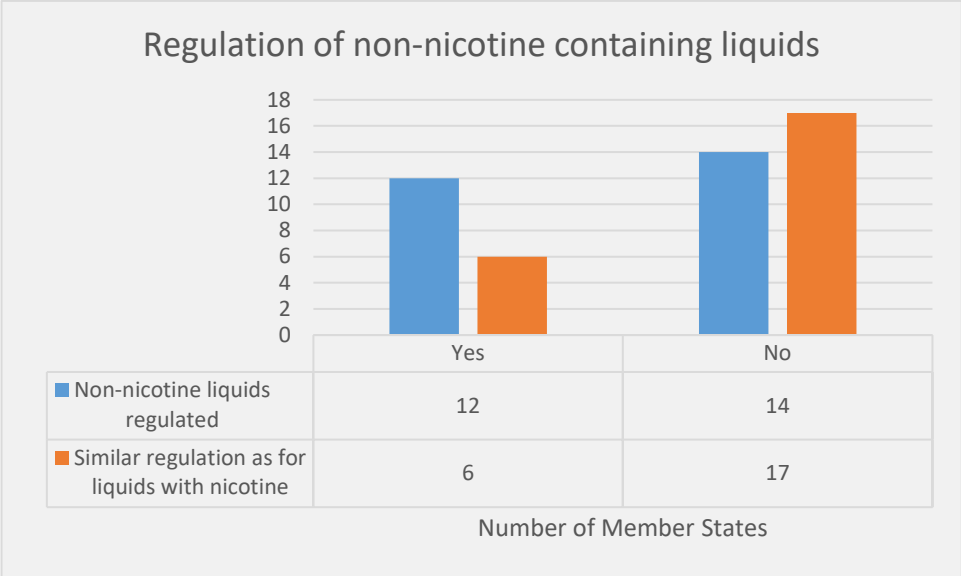

Figure 2

France clarified that for non-nicotine liquids REACH/CLP applies, not the TPD. Norway reported that non-nicotine containing liquids are not regulated for the moment, other than that REACH/CLP applies. There has been a public hearing suggesting banning characteristic flavours in electronic cigarettes (both nicotine containing and nicotine free liquids) with the exception of tobacco flavour. The outcome of this hearing is not finalized. Belgium mentioned that proposal of modification of electronic cigarettes decree which regulates even non-nicotine liquids awaits approval.

Issues with manufacturers and importers

The size of the European market of novel tobacco products, e-cigarettes and refill containers is increasing with a significant online sales[3]. In order to achieve a smooth functioning of the internal market of products that comply with the TPD requirements, manufacturers and importers play the crucial role and bare the responsibilities relating to the compliance of these products.

Issues regarding notifications of e-cigarettes

Seventeen Member States (17/26: BE, CZ, AT, FI, IT, EE, PT, FR, LV, ES, PL, DE, DK, GR, HU, MT, IE) identified issues regarding product notifications with manufacturers and importers of e-cigarettes and refill containers. Several of the

[3] FTC Report Finds Annual Cigarette Sales Increased for the First Time in 20 Years

above-mentioned Member States explained that the primary reasons for these issues were incomplete, incorrect or missing information in the product notifications:

- not all the ingredients are notified (FR, CZ, LV, ES, DE, IE),
- incorrect launch date (FI, LV),
- incorrect nicotine concentration (GR, IT),
- incorrect language of the health warnings (IT),
- incorrect volume capacity (IT, ES),
- incorrect brand name (IT),
- presence of forbidden ingredients - menthol (FI),
- lack of necessary attachments such as reports, test results (PT, FI, LV, DE),
- lack of quality and safety declaration (PT, FI, LV, DE),
- lack of toxicological data (LV, DE, PL),
- missing or incorrect information on sales volumes (FR, DE, DK),
- missing or incorrect information on annual sales data (DK, DE),
- missing information on responsible economic operator in the EU (LV),
- no payment of fees for product notifications (PT, NL).

In addition to the above-mentioned identified issues, several Member States faced challenges with the submitted information in the EU-CEG. Latvia presented several examples of non-compliances and poorly submitted information related to product notifications, these include incorrect classification of the ingredients, reported emissions in tests reports that did not match the information submitted in the EU-CEG, the total amount of ingredients added to the recipe in mg that did not match the individual weight, missing reference to tested product ID, missing submission of nicotine salts..

Germany noted problems with incomplete entries in the product notifications in EU-CEG and specified which fields this mostly concerned, such as sub-brand name, product structure, technical data on refill containers with regard to material and lid closure. Germany pointed out that, to their knowledge, naming of the function of the ingredient is inaccurate and, in some cases, documents on toxicological data are missing.

Poland reported that they faced issues with manufacturers and importers of e-cigarettes and refill containers such as lack of information on ingredients, in particular on flavourings, attached pdf files in wrong places of the submission. Spain mentioned problems with product duplications in the EU-CEG. According to Denmark, the product notifications, in general, have been compliant. Denmark mentioned issues regarding child safety locks or volume capacity. Ireland mentioned missing information regarding ingredient and emission.

Issues regarding notifications of novel tobacco products

Fifteen Member States (15/26: SE, DK, SI, SK, FI, PL, NO, BG, LV, LT, ES, HR, NL, EE, CY) reported that they have not had any issues regarding content of product notifications with manufacturers and importers of novel tobacco products.

Eight Member States (8/26: BE, CZ, AT, FR, DE, PT, HU, IT) highlighted that they faced issues with manufacturers and importers of novel tobacco products regarding:

- incomplete and/or incorrect submitted data,
- poor quality or inadequate attached documentation,
- submissions under wrong product type,
- wrong launch date,
- lack of toxicological data or emissions.

Several Member States faced challenges with the submitted information on novel tobacco products in the EU-CEG. Belgium reported that industry reports are not transparent, submitted information is often dated or concerns other subtypes than the product that has been notified. In addition, the submitted data was reported in other languages.

Germany pointed out that sometimes there is no specific emission data for a product but just exemplary emission data of a prototype. Some manufacturers argue that it is sufficient if the EU-CEG notification is performed after the product was authorized. In that case all required information are provided via CD/DVD.

Czech Republic faced issues with missing information in the notification of the novel tobacco products, such as the studies, the description of the product, use instructions, emissions. According to Austria, most of the issues with the manufacturers and importers of novel tobacco products were regarding attached documentation. Poland noted such issues as lack of detailed description of novel tobacco products, lack of any toxicological data. Italy informed that Customs rejected notification of a novel tobacco product containing CBD.

Actions against manufacturers and importers

When EU Member States perform their regulatory and enforcement tasks, it is necessary for the Member States to have access to the comprehensive information on notified tobacco and related products such as ingredients, sales volume, mode of sales, suspected adverse effects, etc. Therefore, it is necessary that manufacturers and importers of tobacco and related products provide such information through the EU-CEG so that EU Member States can take to appropriate actions and eliminate the EU market from non-compliant and/or dangerous products.

Incomplete and incorrect notifications

The Member States were asked whether they require completion of notification information in case of an incorrect and/or incomplete submission of novel tobacco products, e-cigarettes and refill containers. All Member States with the exception of Netherlands, Slovakia and Sweden responded that they require completion of

notification information. Finland noted that they require completion if the resources allow.

Eighteen Member States (18/26: BE, CZ, AT, LT, SI, HR, SE, IT, PT, FR, LV, PL, ES, DE, DK, HU, MT, IE) reported that they have already taken actions towards manufacturers and importers of e-cigarettes and refill containers and required to complete and/or correct product notifications. Several Member States provided examples of taken measures.

Latvia mentioned that in 2021 they started to flag incomplete and/or incorrect submissions in the EU-CEG. Belgium reported that submitters are given the opportunity to correct and/or complete their submission, information on non-compliant products is published on the responsible authority's web site in the "negative list" and follow up non-compliances during inspections.

Czech Republic stated that in cases of missing or incomplete information in the product notifications, inspections are carried out by Regional Public Health Authorities. In Austria, if during a control national control bodies find that a product has not been notified adequately, the national administrative penal authorities are guided by the Ministry to initiate and carry out legal proceedings. Malta contacts the submitter prior to placing on the market.

Lithuania mentioned that they request the manufacturer or importer to submit correct/complete information or withdraw the product from the EU-CEG system. If manufacturer or importer does not fulfil that requirement, the responsible authority will proceed with flagging of the product notification in the EU-CEG and withdrawal of the product from the active products list. Ireland reported if products are not notified they have used powers to remove products from the market.

Several Member States (HR, IT, ES, PT, PL) reported that they, as a rule, require the manufacturers and importers to complete and/or correct the notification. According to Poland, more than half of the manufacturers and importers make correction after authority's requirements.

According to Germany, it depends on the competent authority at the manufacturer's headquarters. Some manufacturers are requested to provide the missing data in writing, while others, got their products blocked on site and officially sealed. In the case of a customs import, the import will be refused.

Denmark enforces marketing bans in case of non-compliance regarding e.g. child protection or volume capacity, and a fine if the marketing ban is not complied with.

Non-compliant products

All Member States, except Norway a non-EU Member State which has not yet implemented the TPD, provided information regarding actions taken against manufacturers and importers of novel tobacco products, e-cigarettes and refill

containers in case of non-compliance. Usually, the Member States required product withdrawal and fines, followed by requirements for product modification/correction, see *figure 3*.

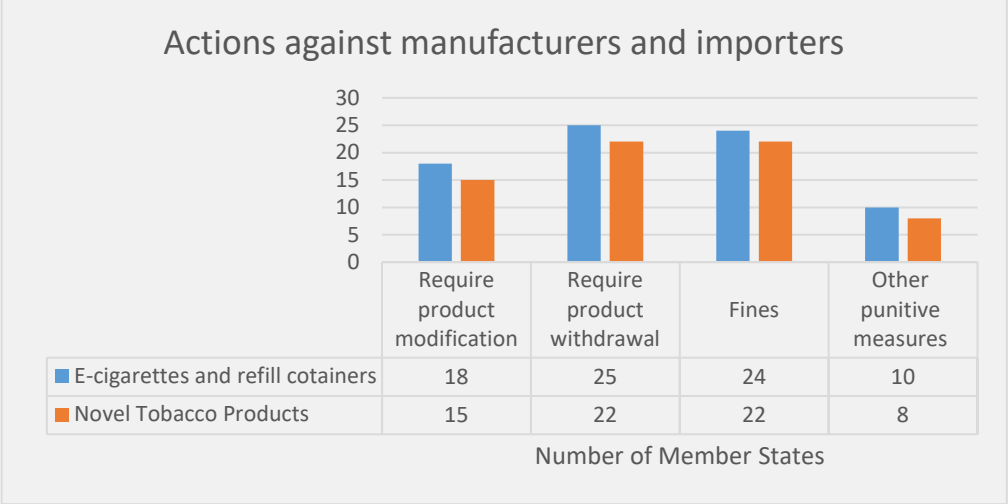

Figure 3

Several Member States shared information on other punitive measures taken against manufacturers and importers of novel tobacco products, e-cigarettes and refill containers. Czech Republic pointed out that the powers of market surveillance, investigation and enforcement can be taken by the Member States according to Article 14 of Regulation (EU) 2019/1020. Member States may exercise these powers different ways, such as to require manufactures and importers to provide relevant documentation, data or information on compliance and technical aspects of the product, to take appropriate actions in order to bring a non-compliance to an end or eliminate a risk etc.

Bulgaria mentioned that if a manufacturer or importer fails to comply with the authority's request, the enforcement body shall issue orders with mandatory instructions for the manufacturers, importers and retailers to recall such products from the market. In cases where manufacturers, importers and retailers fail to comply with such order, the control body shall confiscate and destroy non-compliant products.

In Austria, with the Ministry's communication to the administrative penal authorities, the Ministry informs also the manufacturers and importers about the results of the control and the violation of national law. The entrepreneurs are also asked to inform the Ministry of the measures they have taken to (re)establish the legal situation. If companies do not inform the Ministry, a renewed inspection will be carried out.

Ireland reported other punitive measures such as recall, bringing product into compliance, destruction of product, take possession of product, prohibition order, compliance notice, prosecution, require information, take copies of documents, remove documents, detain products on site, secure any part of a premises for later

inspection, enter a dwelling with a warrant, controls on imports under Regulation 2019/1020, actions can be taken regarding breaches on websites.

Several Member States mentioned other punitive measures such as product bans (SE, DK), products can be seized (MT) and even sentence to prison (PL).

Publicly available information on a website

Member States shall ensure that the information on submitted notifications received from manufacturers and importers of novel tobacco products, e-cigarettes and refill containers is made publicly available on a Member States' website. Besides, Member States should make sure to take trade secrets duly into account when making that information publicly available. Several Member States provided links to their publicly available information on notified novel tobacco products, e-cigarettes and refill containers, see *Table 5*.

Member State	E-cigarettes and refill containers	Novel tobacco products
Croatia	Ministarstvo zdravstva Republike Hrvatske - Popis e-cigareta i spremnika za ponovno punjenje prijavljenih Ministarstvu zdravstva kroz EU CEG (zajedničko mjesto elektroničkog ulaza EU-a) (gov.hr)	Ministarstvo zdravstva Republike Hrvatske - Popis duhanskih proizvoda prijavljenih Ministarstvu zdravstva kroz EU CEG (zajedničko mjesto elektroničkog ulaza EU-a) (gov.hr)
Slovakia	Link was not provided	Link was not provided
Netherlands	No publicly available information on a website	No publicly available information on a website
Slovenia	Reporting on tobacco and related products (tobak.si)	Reporting on tobacco and related products (tobak.si)
Bulgaria	Министерство на икономиката и индустрията (government.bg)	Министерство на икономиката и индустрията (government.bg)
Finland	Valvira: Tupakkarekisteri	No publicly available information on a website
Lithuania	El cig tvarka angl 4.pdf (lrv.lt)	El cig tvarka angl 4.pdf (lrv.lt)
Austria	Office for Tobacco Coordination - § 8 Publication - AGES	Büro für Tabakkoordination - Zulassung neuartiger Tabakerzeugnisse - AGES
Belgium	Notification des produits de la e-cigarette | SPF Santé publique (belgium.be)	Link was not provided
Czech Republic	Bylinné výrobky určené ke kouření, elektronické cigarety a náhradní náplně do nich, které výrobci a dovozci oznámili prostřednictvím elektronické vstupní brány pro předkládání informací (EU-CEG) – Ministerstvo zdravotnictví (mzcr.cz)	Státní zemědělská a potravinářská inspekce | Informační povinnost - Seznam tabákových výrobků a bylinných výrobků určených ke kouření (gov.cz)
Spain	Ministerio de Sanidad - Profesionales - PRODUCTOS COMERCIALIZADOS ESPAÑA - TABACO	Productos_Tabaco_Espana.pdf (sanidad.gob.es)
Italy	Gli Ingredienti dei Prodotti del Tabacco e delle Sigarette Elettroniche –	Gli Ingredienti dei Prodotti del Tabacco e delle Sigarette Elettroniche – Ministero

Member State	E-cigarettes and refill containers	Novel tobacco products
	Ministero della Salute (ingredientiprodottideltabacco.it)	della Salute (ingredientiprodottideltabacco.it)
Sweden	Publicly available information on electronic cigarettes and refill containers - The Public Health Agency of Sweden (folkhalsomyndigheten.se)	Publicly available information on tobacco products - The Public Health Agency of Sweden (folkhalsomyndigheten.se)
Estonia	https://www.terviseamet.ee/sites/default/files/KTO/Tubakatooted/eestis_teavitatud_e-sigaretid_seisuga_28.02.2022.xlsx	eestis_teavitatud_tubakatooted_k.a_uudsed_tubakatooted_seisuga_28.02.2022.xlsx (live.com)
Portugal	Link was not provided	No publicly available information
Germany	BVL - Listung von Tabakerzeugnissen und E-Zigaretten (bund.de)	www.bvl.bund.de/tabaklisten only authorized novel TP are listed
France	Vaping products | Anses - Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail	Tobacco and related products | Anses - Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail
Cyprus	Υγειονομική Υπηρεσία (moh.gov.cy)	Link was not provided
Latvia	EU-CEG Latvijas datu repozitorijā paziņotie tabakas izstrādājumi, elektroniskās cigaretes un uzpildes flakoni | Veselības inspekcija	EU-CEG Latvijas datu repozitorijā paziņotie tabakas izstrādājumi, elektroniskās cigaretes un uzpildes flakoni | Veselības inspekcija
Poland	Papierosy elektroniczne i pojemniki zapasowe - Biuro do spraw Substancji Chemicznych - Portal Gov.pl (www.gov.pl)	Wyroby tytoniowe - Biuro do spraw Substancji Chemicznych - Portal Gov.pl (www.gov.pl)
Denmark	List of registered e-cigarette products | Sikkerhedsstyrelsen	List of registered tobacco products | Sikkerhedsstyrelsen
Norway	Not relevant until the enter into force of the TPD	No publicly available information on a website (not relevant, no products has so far been authorized)
Greece	https://www.moh.gov.gr/articles/health/domes-kai-draseis-gia-thn-ygeia/antimetwpish-eksarthsewn/c680-anakoinwseis/10408-e-cigarettes	https://www.moh.gov.gr/articles/health/domes-kai-draseis-gia-thn-ygeia/antimetwpish-eksarthsewn/c680-anakoinwseis/10407-tobacco-products
Hungary	Under construction	No publicly available information
Malta	Tobacco and related products notified under LN67 of 2016 (gov.mt)	Tobacco and related products notified under LN67 of 2016 (gov.mt)
Ireland	No publicly available information	No publicly available information

Table 5

Published information on e-cigarettes

The Member States were asked which information on e-cigarettes and refill containers is publicly available in their country. *Table 6* gives an overview of the publicly available information for each country.

Publicly available information	**BE**	**CZ**	**AT**	**LT**	**FI**	**BG**	**NO**	**SI**	**NL**	**SK**	**HR**	**SE**	**IT**	**EE**	**PT**	**FR**	**CY**	**LV**	**ES**	**DE**	**PL**	**DK**	**GR**	**HU**	**MT**	**IE**
Name, contact details of manufacturer	*		*	X	X	X		*			X	X		X						X	*	X			x	

Publicly available information	BE	CZ	AT	LT	FI	BG	NO	SI	NL	SK	HR	SE	IT	EE	PT	FR	CY	LV	ES	DE	PL	DK	GR	HU	MT	IE
Responsible legal/natural person				X						X									X							
Importer into the Member State			*	X		X		*		X	X	X							X	X						
Ingredients				X								X	X			X										
Emissions				X				X				X														
Toxicological data				X									X													
Nicotine doses			X	X				X					X	X		X			X		X				X	
Components of the product				X									X													
Production process				X																						
Quality & safety declaration				X												X										
Annual sales volume							*			X																

Table 6

(*) Austria, Belgium and Slovenia indicated that contact details of manufacturer and importer are not publicly available. Poland and Malta noted that only name and contact details of manufacturer are published. Norway noted that nicotine-containing e-cigarettes are not allowed to be sold by retailers on the national market.

Several Member States reported other additional information on e-cigarettes and refill containers that is made publicly available:

- Submitter Name (CZ, LV, DE, DK, GR, BE)
- Submitter Type (CZ, SE, DE, MT)
- Submitter Country (CZ, DE, MT)
- First Submission Date (CZ, FI, EE, LV, DK, MT)
- Launch Date(s) (CZ, SE, LV)
- Last Submission Update (CZ, MT)
- Product id (BE, CZ, SE, EE, LV, ES, DK, MT)
- Brand Name(s) (BE, CZ, FI, SE, EE, LV, ES, DE, PL, DK, GR, MT)
- Brand Sub Type Name(s) (BE, CZ, FI, SE, EE, LV, ES, DE, PL, DK, GR, MT)
- Product Type (BE, CZ, FI, SE, EE, LV, DE, PL, DK, GR, MT)
- Liquid volume (AT, SE, IT, ES)
- Nicotine concentration (SE, ES).

Austria highlighted that only name of the submitter is published. Poland responded that only name of the manufacturer is publicly available on the responsible authority's website. Slovenia mentioned that contact details of manufacturers and importers are not publicly available. Portugal stated that brands are considered confidential. Italy reported that they publish information on coil composition and battery type. Cyprus publishes a list of products to be imported in Cyprus. Norway

mentioned that they have so far not taken a position on this issue. Hungary mentioned that it is under construction.

Published information on novel tobacco products

Not all the Member States have fully enforced the provision regarding publicly available information on notified novel tobacco products, see *table 7.* Four Member States (NL, FI, PT, HU) reported that they did not have information on novel tobacco products publicly available on their web sites.

Publicly available information	BE	CZ	AT	LT	FI	BG	NO	SI	NL	SK	HR	SE	IT	EE	PT	FR	CY	LV	ES	DE	PL	DK	GR	HU	MT	IE
Name, contact details of manufacturer		*	*	X		X		X			X	X		X						X	*					
Responsible legal/natural person				X						X									X							
Importer into the Member State				X		X		X		X	X	X								X						
Ingredients				X								X	X			X										
Emissions			X	X				X				X	X						X							
Annual sales volume				X						X																

Table 7

(*) Austria, Czech Republic and Poland indicated that only name of the submitter is publicly available.

Several Member States reported other additional information on novel tobacco products that is made publicly available:

- Last Submission Update (CZ)
- First Submission Date (CZ, LV)
- Submission Type (CZ)
- Brand Name(s) (BE, CZ, SE, LV, ES, DE, PL, DK, GR)
- Brand Sub Type Name(s) (BE, CZ, SE, LV, ES, DE, PL, DK, GR)
- Launch Date(s) (BE, CZ, SE, LV)
- Withdrawal date(s) (CZ)
- Product Type (CZ, SE, LV, DE, DK, GR)
- Product ID (SE, LV, DK)
- Package (CZ, SE, DK, GR)
- Tobacco weight (IT)
- Presence of filter (IT)
- Total weight (IT).

Four Member States (SI, PL, AT, CZ) reported that only name of the submitter is published, contact details of the manufactures and importers of novel tobacco products are not publicly available in these countries.

In Belgium, information about the product will be published as soon as a novel tobacco product is validated by the responsible authority. In Cyprus, a list of products to be imported is published.

Issues regarding publishing of information

Twenty Member States (20/26: AT, BE, CZ, SE, IT, HR, LV, LT, SI, SK, BG, PL, DK, ES, CY, FR, PT, NL, FI, MT) responded that they have not had any issues with manufacturers and importers of e-cigarettes and refill containers regarding the publishing of information that can be considered a trade secret or otherwise confidential.

Estonia indicated that they had issues regarding country of production, which were not specified. Germany mentioned that their list of notified e-cigarettes and refill containers does not contain information on ingredients or other specific information. Germany pointed out that they faced some challenges when manufacturers, importers and retailers of e-cigarettes and refill containers ignore the period of six months and put their products on the market before this period has passed. Ireland mentioned that currently they are not publishing information on notified e-cigarettes to the Health Service Executive.

Twenty-two Member States (22/26: AT, BE, CZ, SE, IT, HR, LV, LT, SI, SK, BG, PL, DK, ES, CY, FR, PT, NL, FI, DE, EE, GR) reported that they did not have any issues either with manufacturers and importers of novel tobacco products regarding publishing of information that may be considered a trade secret or otherwise confidential.

Product ban

Member States shall ensure that tobacco and related products comply with the requirements set out in the TPD. Manufacturers and importers should bear the responsibilities for these products relating to the compliance and safety. Therefore, it is necessary to ensure that Member States have necessary instruments to protect the internal market from non-compliant products and/or products that poses potential health and safety risks.

Fifteen Member States (15/26: BE, CZ, AT, LT, HR, SE, IT, CY, ES, PL, DK, HU, MT, IE) reported that they have rejected/banned/forbidden/withdrawn e-cigarettes and refill containers from their national markets. Seven Member States (7/26: PL, BE, CZ, AT, LT, IE, IT) made information on rejected/banned/forbidden/withdrawn e-cigarettes and refill containers publicly available and provided links, see *table 5*.

Seven Member States (7/26: AT, CR, CY, PL, DK, HU, IT) reported that they have rejected/banned/forbidden/withdrawn novel tobacco products. For Norway, a non-EU member state, this was relevant only for novel nicotine products when the questionnaire was filled out. If a new product is authorized for the market this

information will be made publicly available. Applications for approval that have been denied will be made public on The Directorate of Health webpage as soon as the result is final. Cyprus made information on rejected/banned/forbidden/ withdrawn novel tobacco products publicly available and provided links, see *Table 8*.

Member State	E-cigarettes and refill containers	Member State	Novel tobacco products
Belgium	Notification des produits de la e-cigarette | SPF Santé publique (belgium.be)	Cyprus	Υγειονομική Υπηρεσία (moh.gov.cy)
Czech Republic	Nebezpečné výrobky – 7. stránka – Ministerstvo zdravotnictví (mzcr.cz)	Latvia	Elektronisko smēķēšanas ierīču un to uzpildes šķidrumu markējums un tirdzniecības vietā izvietojamā informācija | Veselības inspekcija
Lithuania	Pakeitimai 2022-07-01 angl.pdf (lrv.lt)		
Poland	Wykaz wydanych decyzji - Biuro do spraw Substancji Chemicznych - Portal Gov.pl (www.gov.pl)		
Austria	Produktwarnungen & Produktrückrufe - AGES		
Ireland	Information is available on the Health Service Executive website		
Italy	https://www.adm.gov.it/portale/tabacchi-determinazioni-provvedimenti-gu		

Table 8

Specific requirements

Diverging legislation and practices regarding novel tobacco products, e-cigarettes and refill containers exist between the Member States. In order to enable Member States to carry out their surveillance tasks and ensure a high level of public health protection, Member State have to introduce specific requirements for emerging products and potential health and safety risks that these products can pose.

Specific requirements for e-cigarettes

Seventeen Member States (17/26 BE, CZ, AT, FI, BG, SI, NL, HR, SE, IT, EE, PT, CY, LV, ES, DE, HU) consider that their national regulations cover all the aspect of e-cigarettes and refill containers. Few Member States mentioned which aspects of e-cigarettes and refill containers are not covered by their national regulations, such as non-nicotine products (FR, PL, MT, IE), products used for smoking cessation (DK) and e-cigarettes that can be modified by the end user (IE).

Two Member States (NL, DK) mentioned new specific requirements for e-cigarette devices. The Netherlands introduced requirements for devices containing non-

nicotine liquid. Denmark mentioned two new guidelines that specify interpretation of the requirements of child protection and product presentation.

The Member States were asked whether they introduced any other specific requirements related to e-cigarettes and refill containers apart from the TPD. Ten Member States (10/26: CZ, AT, LT, EE, SI, IT, PL, DK, HU, MT) responded that they introduced such requirements. Czech Republic mentioned requirements related to nicotine-free e-cigarettes and refill containers that are similar to nicotine containing products. Austria mentioned that requirements for nicotine-containing liquids also apply to nicotine-free liquids. Estonia mentioned prohibition of flavours. Latvia apply the same requirements to nicotine-free liquids and devices as to e-cigarettes and refill containers with the exception of notification to EU-CEG and fees for processing information. Hungary mentioned that e-liquids must not contain both nicotine and flavourings at the point of sale. Malta reported that vaping ban in all areas and also advertising prohibitions as for other tobacco products.

Slovenia presented several new requirements related to use, trade and marketing of e-cigarettes and refill containers including prohibition of use of e-cigarettes in public and work places, vehicles; a ban on selling to minors, distance sale, sales from vending machines and mobile points; marketing ban; a ban on manufacturing and placing on the market sweets, snacks toys or other items in the shape of e-cigarettes; license requirement for retailers.

In Italy, customs apply taxation and impose fiscal stamps to be affixed. Estonia mentioned a ban on flavourings in e-liquids. Latvia introduced the same requirements for nicotine-free liquids and devices as for nicotine-containing e-cigarettes and refill containers with the exception of notification to the EU-CEG and fees for processing information. Poland reported on specific requirements that forbid using these products in public places and sales to minors.

Denmark reported on new requirements for e-cigarettes and refill containers with and without nicotine regarding standardized design including a product ID of individual packages and any outer packaging. Further, prohibition of characteristic flavours other than tobacco and menthol in both nicotine-free and nicotine-containing e-cigarettes and refill containers and also prohibitions of equipment used in connection with e-cigarettes, which makes it possible to change the smell or taste. Denmark mentioned as well requirements regarding notification of refill containers without nicotine prior to marketing and prohibition on showing products (including images) to consumers. Furthermore, Denmark developed a guide that interprets the regulation on product presentation. Ireland mentioned that further regulation is planned and currently being drafted.

Specific requirements for novel tobacco products

Twenty-two Member States (22/26: BE, AT, LT, FI, BG, SI, NL, SK, HR, SE, IT, EE, PT, FR, CY, LV, ES, DE, PL, DK, GR, IE) do not regulate any (new) products that are not covered by the TPD definition of novel tobacco products. Czech

Republic mentioned regulations on tobacco-free nicotine pouches. Hungary reported ban on using novel tobacco products in all enclosed public places and workplaces, ban on advertising, ban on cross-border and only can be sold in national tobacco stores.

Member States were asked if they introduced any specific requirements for novel tobacco products devices. Two Member States (FI, HR) mentioned such requirements. Finland reported on pending display ban. Croatia mentioned that it is prohibited to advertise or promote those products that are not considered to be tobacco products but whose shape, name or intended purpose indirectly encourage the consumption of those products. Latvia responded that, after the 1st of July 2022, the devices are regulated in the same way as e-cigarettes. According to the Austrian legal view, the plugs and the device are a complete system and therefore the same provisions apply to the device as to the capsules.

The Member States were asked whether they introduced any other specific requirements related to novel tobacco products apart from the TPD. Six Member States (6/26: BE, AT, SI, NL, HR, PL) provided information on different specific requirements. For example, in Belgium, devices for novel tobacco products should be notified as well. Austria introduced ban on advertising of tobacco and related products including devices for novel tobacco products, the ban includes not only TV and radio but also social media.

Slovenia presented several new requirements related to use, trade and marketing of novel tobacco products similar to the requirement for e-cigarettes and retail containers mentioned in the previous section. New regulations forbid use of novel tobacco products in public and work places, vehicles. Moreover, they introduced a ban on selling to minors, distance sale, sales from vending machines and mobile points; a marketing ban; a ban on manufacturing and placing on the market sweets, snacks toys or other items in the shape of novel tobacco products; and a license for retailers.

The Netherlands mentioned that after July 1st 2022, novel tobacco products devices are regulated in the same way as e-cigarettes. The Netherlands mentioned also general provisions that apply to all tobacco and related products such as an age limit, the ban on advertising and promotion, display ban, restrictions on points of sales, and a smoking ban. Croatia reported that it is prohibited to smoke tobacco and related products including herbal products or waterpipe tobacco, and to use nicotine-containing or non-nicotine containing e-cigarettes in all indoor public places with the exception of specially designated smoking areas. Poland mentioned a smoking ban in public places and a ban on sales to minors. Denmark provided information on requirements for standardized design of individual packages and any outer packaging for novel tobacco products, prohibition on showing products (including images) to consumers.

Information leaflets and health warnings

The labelling and packaging of e-cigarettes and refill containers should display sufficient and appropriate information on their safe use, in order to protect human health and safety; they should carry appropriate health warnings and should not include any misleading elements or features. In view of the fact that nicotine is a toxic substance and considering the potential health and safety risks, including to persons for whom the product is not intended, nicotine-containing liquid should only be placed on the market in e-cigarettes or in refill containers that meet certain safety and quality requirements.

None of the responded Member States allows health warnings in other languages than their official language/languages. All Member States except Finland require that both unit packets and outside packaging of refill containers carry health warnings.

Fourteen Member States (14/26: LT, NL, SK, SI, SE, IT, EE, PT, FR, CY, PL, DK, HU, IE) reported that they do not face any issues in implementing the provisions concerning leaflets in unit packets of e-cigarettes. Ten Member States (10/26: LV, ES, DE, HR, BG, BE, CZ, AT, GR, MT) indicated that they experienced different kinds of issues in implementing such provisions concerning leaflets. Belgium mentioned issues regarding leaflets in three national languages.,Malta noted that leaflets do not contain information on safety issues in official languages, English and/or Maltese, Malta is discussing the possibility to include this requirement in their Regulations. Ireland have noted there are a large number of products on the market with no information leaflets which has resulted in action being taken leading to the initiation of RAPEX alerts.

Czech Republic noted that some products do not have a separate information leaflet, instead information from the leaflet is printed on the unit packet. Croatia pointed out that many manufacturers ask to be allowed to put a multi-layer label on refill containers without cardboard packaging.

Latvia noted during supervision that leaflets do not comply with requirements in the TPD, usually information on the leaflets was either missing, not in the official language or incomplete/incorrect. Spain warned for emerging products with QR codes on the packaging instead of information leaflets.

The Member States were asked if all types of novel tobacco products have health warnings. Twenty Member States (20/26: BE, CZ, AT, LT, BG, SI, NL, SK, HR, SE, IT, EE, PT, FR, CY, ES, DE, PL, DK, LV) responded that novel tobacco products have to carry health warnings.

Belgium reported that health warnings are required for all products that are notified, including heated tobacco products. Norway stated that it depends on the product type. In Latvia, all novel tobacco products that are submitted via the EU-CEG and classified as smokeless tobacco products shall carry health warnings.

Other tobacco and related products

In order to ensure that EU legislation on tobacco and related products is fully operational and up-to-date with technical, scientific and market developments, it is necessary for the Member States to follow these developments, gather scientific evidence and research with regard to public health. New emerging nicotine and tobacco products appear on the European market before these products are covered by the regulations. To avoid gaps in regulations caused by new generation of products and products that are not governed by the TPD, the Member States shall share their best practices and experiences by joint actions.

The Member States were asked if they require notification of nicotine pouches, other oral products containing nicotine but not tobacco, products containing CBD and accessories that provide a flavour. Six Member States (6/26: BE, CZ, AT, EE, PT, DK) and Norway require notification of the bellow-mentioned products, see *Table 9.*

Require notification	BE	CZ	AT	NO	EE	PT	DK
Nicotine pouches		x		x			x
Other oral products containing nicotine but not tobacco		x		x		x	
Products containing CBD	x	x	x	x	x		
Accessories that provide a flavour		x					

Table 9

Estonia highlighted that products containing CBD must be notified as herbal product for smoking or e-cigarettes. Portugal mentioned that these products are not covered either by the TPD or by national regulations. Lithuania noted that herbal products, electronic cigarettes and refill containers containing CBD are not allowed.

All EU Member States and Norway, except Greece and Malta, also reported which other tobacco, nicotine and CBD products are available on their national markets, see *Table 10*.

Products available on the market	**BE**	**CZ**	**AT**	**LT**	**FI**	**BG**	**NO**	**SI**	**NL**	**SK**	**HR**	**SE**	**IT**	**EE**	**PT**	**FR**	**CY**	**LV**	**ES**	**DE**	**PL**	**DK**	**GR**	**HU**	**MT**	**IE**
Herbal products with nicotine	X	X		X					?					X	?	X	X	X	X	X	?			X		
Nicotine pouches	X	X	X	*		X	X	X	X	X	X	X	X	X	?	X		X	X	X	X	X		X		X
Other oral products with nicotine, but not tobacco	?	X	X			X			X		X	X		X				X		X						
Products containing CBD	X	X	X	X		X			X	X	X		X	X		X		X	X	X	X	X				X
Accessories that provide a flavour	X	X	X	X	X	X			X			X	X	X	X	X	X	X	X	X	X	X		X		X

Smokeless tobacco (for example snus)	X	*	*				X					X						X		X	X	X			
Other products besides mentioned above		X	X					X								X		X		X					

Table 10

(*) Czech Republic indicated presence of chewing and nasal tobacco, and Austria – presence of nasal tobacco. Lithuania noted that production and/or sale of products whose design imitates tobacco products or their packages is prohibited. Norway reported that they have one nicotine pouch product regulated and sold as medicinal product.

Belgium could not confirm whether other oral tobacco-free nicotine products are available on the Belgian market, but did confirm presence of accessories that provide flavour and smokeless tobacco in spite of bans on these products. Czech Republic also noted nicotine containing and nicotine free heated herbal products.

Austria warned for a new kind of product “Geiles Zeug” (hot stuff), an aroma snuff powder that allegedly has refreshing and stimulating effects. The market strategy of this new product is primarily targeting teenagers and young adults and is consumed nasally (like hard drugs such as cocaine).

In Norway, the ban on characteristic flavours for tobacco products has not yet entered into force, and it is not confirmed whether accessories that provide flavour are present on the market. France mentioned the availability of Shisha Steam Stones on the market.

The Netherlands mentioned that herbal products with nicotine have been notified but the authority does not know for sure if these products are available on the market. Latvia indicated the presence of nicotine containing heated herbal products and CBD pouches. Germany reported on mineral-based products for use in a water pipe, e.g. (nicotine-containing) shisha paste, shisha stones/pearls/crystals.

All Member States and Norway reported which tobacco and nicotine products that are not allowed on their national markets, these products are marked with X in the *table 8*. Ten Member States (10/26: BE, CZ, LT, SK, IT, FR, DE, DK, HU, IE) reported products that are not allowed according to their national regulations, but still appear or appeared on the market in the Member States. These products are marked with red X in *Table 11*.

Not allowed products on the market	**BE**	**CZ**	**AT**	**LT**	**FI**	**BG**	**NO**	**SI**	**NL**	**SK**	**HR**	**SE**	**IT**	**EE**	**PT**	**FR**	**CY**	**LV**	**ES**	**DE**	**PL**	**DK**	**GR**	**HU**	**MT**	**IE**
Herbal products with nicotine										X	X					X										
Nicotine pouches				X	X		X			X			X			X	X			X						
Other oral products containing				X									X			X	X									

nicotine but not tobacco																								
Products containing CBD		x			x						x	x			x							x		x
Accessories that provide a flavour	x						x	x												x		x		
Smokeless tobacco (for example snus)	x	x	x	x	x	x		x	x		x		x	x	x	x	x	x	x		x		x		x
Other products besides mentioned above	x		x												x									x

Table 11

Overwhelming majority of Member States mentioned that snus and oral tobacco are not allowed in their countries. France indicated that nicotine-containing products that are not regulated by the TPD should be regarded as medicines and thus submitted to approval before marketing. Czech Republic specified that only CBD-containing liquids are nor allowed.

Market Surveillance and reporting information

In order to guarantee the free movement of products within the EU, it is necessary to ensure that products are compliant with relevant legislation and therefore fulfil requirements providing a high level of protection of public interests, such as health and safety, and protection of consumers. Market surveillance and enforcement of these requirements are essential to the proper protection of these interests and to create the conditions in which fair competition in the EU markets for goods can thrive. Rules are therefore necessary to ensure this enforcement, regardless of whether products are placed on the market via offline or online means and regardless of whether they are manufactured in the EU or not.

Regulation (EU) 2019/1020 regarding market surveillance and compliance of products entered into force on the 20th of June 2019. This regulation is complementing the existing provisions of the TPD. The Member States were asked if the Regulation (EU) 2019/1020 on market surveillance is implemented. Sixteen Member States (16/26: BE, CZ, AT, LT, SI, BG, HR, EE, FR, LV, ES, DE, DK, HU, SE, IE) confirmed the implementation, six Member States (6/26: PL, CY, IT, SK, NL, FI) informed that Regulation (EU) 2019/1020 has not been implemented yet. Finland indicated that the work on implementation of provisions is in progress.

According to Article 20 of the Regulation (EU) 2019/1020, market surveillance authorities shall use the Rapid Information Exchange System (RAPEX). According to Article 34 of the above-mentioned regulations, information and communication system (ICSMS) shall be used for the collection, processing and storage of information on issues relating to the enforcement of EU harmonisation legislation,

with the aim of improving the sharing of data among Member States. Almost all Member States provided information on which system(s) they use for market surveillance activities and enforcement, see *table 12*.

Reporting system	BE	CZ	AT	LT	FI	BG	NO	SI	NL	SK	HR	SE	IT	EE	PT	FR	CY	LV	ES	DE	PL	DK	GR	HU	MT	IE
ICSMS		X	X		X						X	X	X	X				X	X	X	X	X				X
Rapex		X	X		X	X		X			X	X	X	X			X	X	X	X	X	X		X		X
National system		X		X									X					X	X	X		X		X		X
We do not report	X						X			X						X										

Table 12

Twenty-two Member States (22/26: BE, CZ, AT, LT, FI, BG, NO, SI, SK, HR, SE, IT, EE, FR, CY, LV, ES, DE, PL, DK, HU, IE) provided information regarding how they report or enter information on investigated tobacco and related products. Seventeen Member States (17/26: CZ, AT, FI, BG, SI, HR, SE, IT, EE, CY, LV, ES, DE, PL, DK, HU, IE) reported that they use RAPEX, thirteen Member States (13/23: CZ, AT, FI, HR, SE, IT, EE, LV, ES, DE, PL, DK, IE) use ICSMS. Nine Member States (9/26: CZ, LT, IT, LV, ES, DE, DK, IE) reported using national systems for reporting information on tobacco and related product enforcement.

Discussion and Conclusions

E-cigarettes, refill containers and novel tobacco products gained significant popularity all over the EU Member States in recent years. Differences in general regulations and laws in Member States have their effect on the regulation of tobacco and related products. Studies[4][5][6] show that stronger national tobacco control policies are associated with lower smoking prevalence. With the help of a questionnaire, similarities and differences in national regulatory efforts have been recorded. The questionnaire that has been sent to EU Member States and Norway allowed gaining detailed information about the regulatory landscape of e-cigarettes, refill containers and novel tobacco products from different aspects, covering all general and specific interests of surveillance and public health authorities. The majority of EU Member States (BE, CZ, AT, LT, FI, BG, SI, NL, SK, HR, SE, IT, EE, PT, FR, CY, LV, ES,

[4] Pérez-Stable, Eliseo J., et Erik J. Rodriquez. 2022. « Association of Policy Interventions With Tobacco Use Behaviors ».
[5] "Trends in Smoking Prevalence and Intensity between 2010 and 2018: Implications for Tobacco Control in China" Guoting Zhang, Jiajia Zhan, and Hongqiao Fu,
[6] "The effects of tobacco control policies on global smoking prevalence" Luisa S Flor, Marissa B Reitsma, Vinay Gupta, Marie Ng, Emmanuela Gakidou, Nat. Med. 2021 Feb.

DE, PL, DK, GR, HU, MT, IE) and Norway participated in the questionnaire which constitutes the basis for this report.

To improve the product regulation strategy, it is important to gain a better understanding of product characteristics and market trends. It is the task of the Member States to collect, monitor and analyze submitted data. So the first aspect declared in the report above is the product`s provided information. While some Member States require approval of products before they can enter the market, other Member States allow a notification procedure thanks to notifications submissions from manufacturers and importers at least six months before they intend to place a product on the market. Considering that the approval procedure seems to be stricter than the notification procedure, it would be interesting to get more insights in the approval procedures of Member States. In EU Member States, different institutions are involved in assessing data.

An important tool for the Member States in regulating novel tobacco products and e-cigarettes is banning of ingredients, additives and flavours. Our results show that some ingredients are regulated in certain Member States, but not in others. For example, Finland banned all flavours in e-liquids with the exception of tobacco. Whereas Denmark recently banned all flavours except menthol and tobacco. Norway has a general ban on selling nicotine-containing e-cigarettes until the TPD is implemented and has entered into force. Twenty Member States (20/26: BE, CZ, NL, IT, EE, PT, PL, DE, LT, LT, DK, AT, SE, LV, HU, MT, ES, IE, FR, IT) indicated that their national regulations forbid the ingredients mentioned in the article 7 (6) TPD, like vitamins, caffeine containing ingredients, colouring agents and additives that facilitate inhalation or nicotine uptake. Other Member States should also forbid these ingredients according to the TPD (except NO), but did not report to do so. On the other side, four Member States (26/4: NL, ES, EE, LV) are planning to ban flavours in the near future. In order to improve consumer health protection in the EU, regulation of ingredients should ideally be harmonised. It could be interesting to follow the development of the situation in the different countries which are already banning certain ingredients, in order to gather and learn from their best practices and experiences.

Non-nicotine containing liquids are regulated similarly to nicotine containing liquids by some Member States, while other Member States do not regulate non-nicotine liquids or apply different regulations. Twelve Member States (12/26: CZ, AT, FI, NL, HR, IT, EE, FR, LV, DE, DK, HU) reported that non-nicotine containing liquids are regulated, six of these Member States (6/26: CZ, FI, NL, EE, DE, DK) pointed out that they applied similar provisions for these liquids as for nicotine-containing liquids. More information on regulation of non-nicotine containing e-liquids would be of interest, especially how this impacts the use of nicotine containing e-liquids. Possibly, non-nicotine containing liquids may be used as a legal bypass to use additives or flavours that are forbidden in nicotine containing liquids in some countries. To prevent this, regulators could consider regulating both nicotine

containing and non-nicotine containing liquids under the TPD to ensure harmonisation but also to improve the consumer health protection.

Seventeen Member States (17/26: BE, CZ, AT, FI, IT, EE, PT, FR, LV, ES, PL, DE, DK, GR, HU, MT, IE) pointed out that they have issues with manufacturers and importers regarding products notifications of e-cigarettes and refill containers. The primary reason for these issues are incomplete and/or incorrect notifications, for example due to missing ingredients, incorrect launch dates, lacking quality and safety information or lacking of necessary attachments such as reports and test results. Submitting information on a product in EU-CEG is very complex and can be challenging to use for manufacturers. A systematic examination of the issues can reveal more insights aiming to improve the notification process and offer special assistance for the notification in EU-CEG. The monitoring of notified data is most important to assess products non–compliance with the TPD.

All Member States took actions against manufacturers and importers in case of non-compliances. Seventeen Member States (17/26 BE, CZ, AT, FI, BG, SI, NL, HR, SE, IT, EE, PT, CY, LV, ES, DE, HU) consider that their national regulations cover all the aspects of electronic cigarettes and refill containers. However, for some Member States this was not the case. Currently, these products are regulated on a national level only, as there is no harmonised approach. In order to follow the developments in the market and allow for EU-wide regulatory harmonisation, regulators may consider adding a clause for novel and innovative nicotine containing products to the TPD.

Based on the TPD, Member States have to ensure the greatest possible transparency of product information including ingredients and emission. Therefore, many Member States made the information on submitted notifications received from manufacturers and importers of e-cigarettes, refill container and novel tobacco products publicly available on their website. All Member States defined which information on notified e-cigarettes should be publicly available on their web sites, such as first submission date, launch date, last submission update, liquid volume capacity, nicotine concentration, ingredients and toxicological data etc. Only some Member States follow the request of the greatest possible transparency including ingredients and emissions. Three Member States indicated that they do not have information on novel tobacco products publicly available on their web sites.

Member States shall also ensure appropriate market surveillance. Fifteen Member States (15/26: BE, CZ, AT, LT, HR, SE, IT, CY, ES, PL, DK, HU, MT, IE) reported that they have banned certain e-cigarettes and refill containers from their national market which did not comply with relevant legislation. Some Member States made information on the rejected products publicly available and provided links. Seven Member States (7/26: AT, CR, CY, PL, DK, HU, IT) pointed out that they have rejected novel tobacco products. Two of them (CY, LV) made information on rejected novel tobacco products publicly available and provided links. As of October 2022, four applications on nicotine pouches have been declined by the Directorate

of Health in Norway. Three of them have been appealed to The Ministry of Health for final decision. The Directorate has also declined two applications on HTP.

Diversity in legalisation of novel tobacco products exists between Member States. Member states have to ensure a high level of public health protection through providing specific requirements for emerging products. Six Member States (6/26: BE, AT, SI, NL, HR, PL) provided information on additional specific requirements related to novel tobacco products, e-cigarettes and refill containers apart from the TPD. These include the additional regulation of nicotine-free products, sale ban from vending machines and mobile points of sale, ban on using e-cigarettes in all enclosed public places and workplaces, ban on selling to minors, ban on advertising, promotion and sponsorship, and donations including a display ban on electronic cigarettes and refill containers at points of sale.

Noticeably, faulty labels of e-cigarettes and refill containers are still a cause for concern. At this stage, none of the Member States that responded allows health warnings in other languages than their official language/languages. All responded Member States except Finland require that both unit packets and outside packaging of refill containers carry health warnings. Several Member States noted during enforcement that leaflets do not comply with requirements in the TPD, usually information on the leaflets was either missing or incomplete/incorrect. Spain warned that there are QR codes on the packaging instead of information leaflets.

Other tobacco and nicotine products are available on EU market. Nicotine pouches and accessories that provide flavour to tobacco products are dominating on the European market, followed by products containing CBD, other oral and herbal products containing nicotine. Several Member States highlighted other products emerging on the market. Czech Republic noted nicotine containing and nicotine-free heated herbal products. Austria draws attention to a new kind of product, called “Geiles Zeug” (=hot stuff), which is an aroma snuff powder that allegedly has refreshing and stimulating effects primarily targeting teenagers and young adults.

At the end, Twenty-two Member States (22/26: BE, CZ, AT, LT, FI, BG, NO, SI, SK, HR, SE, IT, EE, FR, CY, LV, ES, DE, PL, DK, HU, IE) provided information regarding how they report or enter information on investigated tobacco and related products. Different information exchange systems are used in Member States like RAPEX or ICSMS without the existence of a European standard program.

Altogether, this report gives an overview of regulation of novel tobacco product and e-cigarettes. It shows that, even when countries have implemented the TPD, many differences exists between MSs in regulation of these products. The information in this report can create awareness of these differences among EU regulators and public health researchers. In addition to the provided information, product use can be followed over time to identify best practices of product regulation in different Member States.

Acknowlegdement

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Appendix

Questionnaire

Country:	
Name (contact person):	
Email (contact person):	
Function:	
Authority/Unit:	

1. **Does your Member State confirm or approve notifications of electronic cigarettes and refill containers prior placing on the market?**

	Yes	No
Confirm reception of notification		
Approve notification of the product		
If other, please elaborate		

2. **Which economic operators are obliged to notify electronic cigarettes and refill containers in your Member State? Mark those that apply:**

Manufacturers	
Importers	
Both manufacturers and importers	

3. **Do regulations in your Member State allow manufacturers and importers of electronic cigarettes and refill containers to launch these products sooner than 6 months prior placing on the market?**

Yes	
No	
If Yes, please specify when (for example directly after submission, after received payment, after the information on this products is publicly available etc.)	

4. Do regulations in your Member State ban flavourings in nicotine-containing liquids?

Yes, we ban all flavourings	
Yes, we ban all flavourings except tobacco	
Yes, but with several exceptions (please specify exception flavourings)	
No	

5. Does your Member State prohibit any other ingredients?

Yes	
No	
If Yes, please specify which ingredients	

6. Is your Member State planning to ban flavourings in nicotine-containing liquids?

Yes	
No	

7. Are non-nicotine containing e-liquids regulated in your Member State?

Yes	
No	

8. Has your Member State applied similar provisions regarding flavourings in non-nicotine containing liquids for electronic cigarettes?

Yes	
No	

9. Have there been any issues regarding content of product notifications with manufacturers and importers of electronic cigarettes and refill containers?

Yes	
No	
If Yes, please elaborate in which aspect, for example incorrect notification etc.	

10. Does your Member State require completion of notification information in case of an incorrect/incomplete submission?

Yes	
No	

11. Has your Member State taken actions towards manufacturers and importers of electronic cigarettes and refill containers regarding incorrect/incomplete submission?

Yes	
No	
If Yes, please elaborate what was the action and the result of this action	

12. Do regulations in your Member State cover all types and aspects of electronic cigarettes and refill containers?

Yes	
No	
If No, describe the product type(s) and/or aspect(s) that are not covered	

13. Has your Member State had any issues with manufacturers and importers of electronic cigarettes and refill containers regarding the publishing of information that they consider a trade secret or otherwise confidential?

Yes	
No	
If Yes, please specify what the issue was and regarding which information	

14. Which actions may competent authorities in your Member State take against manufacturers and importers of electronic cigarettes and refill containers according to your national regulations? Mark those that apply:

Require product modification	
Require product withdrawal	
Fines	

Other punitive measures (please elaborate)	

15. Has your Member State made information on notified electronic cigarettes and refill containers publicly available?

Yes	
No	
If Yes, please provide a link	

16. Which information on electronic cigarettes and refill containers is publicly available in your Member State? Mark those that apply:

The name and contact details of the manufacturer	
A responsible legal or natural person	
The importer into the Member State	
Ingredients	
Emissions	
Toxicological data regarding the product's ingredients and emissions	
Nicotine doses	
Components of the product including opening and refill mechanism	
Production process	
Quality and safety declaration	
Annual sales volume	
Other additional information (please specify)	

17. Has your Member States rejected/banned/forbidden/withdrawn a product?

Yes (if Yes, proceed to Question 18)	
No (if No, proceed to Question 19)	

18. Has your Member State made information on rejected/banned/forbidden/withdrawn electronic cigarettes and refill containers publicly available?

Yes	

No	
If Yes, please provide a link	

19. Has you Member State introduced any specific requirements for electronic cigarette devices?

Yes	
No	
If Yes, please elaborate	

20. Has your Member State introduced any other specific requirements related to electronic cigarettes and refill containers apart from the TPD?

Yes	
No	
If Yes, please elaborate	

21. Do regulations in your Member State contain requirements for health warnings in other languages than official language/languages?

Yes	
No	

22. Do both unit packets and outside packaging of refill containers have to carry health warnings?

Yes	
No	

23. Has your Member State faced any issues in implementing the provisions concerning leaflets in unit packets of electronic cigarettes?

Yes	
No	
If Yes, please elaborate	

24. Does your Member State confirm or approve notifications of novel tobacco products prior placing on the market?

	Yes	No

Confirm reception of notification		
Approve notification of the product		
If other, please elaborate		

25. Which economic operators are obliged to notify novel tobacco products in your Member State? Mark those that apply:

Manufacturers	
Importers	
Both manufacturers and importers	

26. Do regulations in your Member State allow manufacturers and importers of novel tobacco products to launch their products sooner than 6 months prior placing on the market?

Yes,	
No	
If Yes, please specify when (for example directly after submission, after received payment, after the information on this products is publicly available etc.	

27. Have there been any issues regarding content of product notifications with manufacturers and importers of novel tobacco products?

Yes	
No	
If Yes, please elaborate in which aspect, for example incorrect notification etc.	

28. What types of novel tobacco products have been notified to your competent authority in your Member State?

Smokeless tobacco products (please provide brand names)	
Tobacco products for smoking (please provide brand names)	

Heated tobacco products (please provide brand names, for example IQOS, Heet Sticks)	
Other (please provide brand names)	

29. Does your Member State require completion of notification information in case of an incorrect/incomplete submission?

Yes	
No	

30. Has your Member State requested additional information or tests on specific novel tobacco products?

Yes	
No	
If Yes, please specify for which products	

31. Do your national regulations cover any (new) products that are not covered by the TPD definition of Novel Tobacco Products?

Yes	
No	
If Yes, please specify for which products	

32. Has your Member State made information on notified novel tobacco products publicly available?

Yes	
No	
If Yes, please provide a link	

33. Which information on novel tobacco products is publicly available in your Member State? Mark those that apply:

The name and contact details of the manufacturer	
A responsible legal or natural person	

The importer into the Member State	
Ingredients	
Emissions	
Annual sales volume	
Other additional information (please specify)	

34. Has your Member States has rejected/banned/forbidden/withdrawn a product?

Yes (if Yes, proceed to Question 35)	
No (if No, proceed to Question 36)	

35. Has your Member State made information on rejected/banned/forbidden/withdrawn novel tobacco products publicly available?

Yes	
No	
If Yes, please provide a link	

36. Has your Member State had any issues with manufacturers and importers of novel tobacco products regarding publishing of information that they consider a trade secret or otherwise confidential?

Yes	
No	
If Yes, please specify what the issue was and regarding which information	

37. Has your Member State prohibited any ingredients in novel tobacco products?

Yes	
No	
If Yes, please specify which ingredients	

38. Do all types of novel tobacco products have health warnings?

Yes	

No	
If No, please specify which novel tobacco products do not carry health warnings	

39. Has you Member State introduced any specific requirements for novel tobacco products devices?

Yes	
No	
If Yes, please elaborate	

40. Has your Member State introduced any other specific requirements related to novel tobacco products apart from TPD?

Yes	
No	
If Yes, please elaborate	

41. Which actions may competent authorities in your Member State take against manufacturers and importers of novel tobacco products according to your national regulations? Mark those that apply:

Require product modification	
Require product withdrawal	
Fines	
Other punitive measures (please elaborate)	

42. Does your Member State require notification of the following products?

	Yes	No
Nicotine pouches		
Other oral products containing nicotine but not tobacco		
Products containing cannabidiol (CBD)		
Accessories that provide a flavour		
If there are any other products besides mentioned above (please elaborate)		

43. Which of the products are available or were available on the market in your Member State? Mark those that apply:

Herbal products with nicotine	
Nicotine pouches	
Other (oral) products containing nicotine but not tobacco	
Products containing cannabidiol (CBD)	
Accessories that provide a flavour	
Smokeless tobacco (for example snus)	
If there are any other products besides mentioned above (please elaborate)	

44. Which of tobacco and related products are not allowed in your Member State?

Herbal products with nicotine	
Nicotine pouches	
Other (oral) products containing nicotine but not tobacco	
Products containing cannabidiol (CBD)	
Accessories that provide a flavour	
Smokeless tobacco (for example snus)	
If there are any other products besides mentioned above (please elaborate)	

45. Does your Member State regulate other tobacco and related products for consistency?

Yes	
No	
If Yes, please elaborate	

46. Is Regulation (EU) 2019/1020 on market surveillance and compliance of products implemented in your Member State?

Yes	
No	

47. How does your Member State report/enter information on investigated tobacco and related products? Mark those that apply:

ICSMS (Information and Communication System on Market Surveillance)	
Rapex (Rapid Information Exchange System)	
National system	
We do not report/enter information	

German list of prohibited ingredients in novel tobacco products

1. Vitamins or the following other additives that create the impression that a tobacco product has a health benefits or pose lower health risks:

a) amino acids and modified amino acids which, pursuant to Section 7(1), first sentence, no. 1 in conjunction with in conjunction with Annex 2, Category 3 of the Dietary Regulation, as amended from time to time. as well as S-adenosylmethionine and L-5-hydroxytryptophan.

b) Carnitine, L-carnitine, L-carnitine hydrochloride, L-carnitine L-tartrate

c) flavonoids and antioxidant phospholipids

d) sodium selenite

2. Caffeine, taurine or the following other additives and stimulant mixtures associated with energy and vitality:

a) maltodextrin

b) ingredients, including processed ingredients, extracts and oils of the coffee plant and the coffee beans

c) ingredients including processed ingredients, extracts and oils of the tea shrub Camellia sinensis L. Kuntze

d) constituents, including processed constituents, extracts and oils of the guarana plant

e) constituents including processed constituents, extracts and oils of the mate plant

f) thujone

3. Additives having coloring properties for emissions

4. The following additives in smoking tobacco products* that facilitate inhalation or nicotine uptake facilitate:

a) p-menthane-3-substituted and modified compounds, including:

p-menthane-3-carboxamides, including p-menthane-3-N-alkylcarboxamides

p-menthane-3-esters

p-menthane-3-ether

p-menthane-3-carboxylic acids and their esters

menthone 1,2-glycerol ketal (CAS No. 63187-91-7)

b) p-menthane alcohols and their esters

c) the following compounds:

3,4-Dihydro-3-(2-hydroxyphenyl)-6-(3-nitrophenyl)-(1H)-pyrimidin-2-on (CAS-Nr. 36945-98-9)

2-isopropyl-N 2,3-trimethylbutyramide (CAS No. 51115-67-4)

Isopulegol (CAS No. 7786-67-6 or CAS No. 89-79-2)

1-(di-sec-butyl-phoshinoyl)-heptane

d) the following substances:

(aa) menthol (CAS No. 1490-04-6).

(-)-menthol (CAS No. 2216-51-5)

(+)-Menthol (CAS No. 15356-60-2)

bb) Menthone (CAS No. 89-80-5)

(-)-menthone (CAS No. 14073-97-3)

(+)-menthone (CAS No. 3391-87-5)

L-carvone (CAS No. 6485-40-1)

Geraniol (CAS No. 106-24-1)

Linalool (CAS No. 78-70-6)

1,8-cineole (eucalyptol) (CAS No. 470-82-6)

hydroxycitronellal (CAS No. 107-75-5)

e) the following substances derived from plants:

Oils and constituents derived from plants of the genera Mentha, Eucalyptos, Ocimum, Thymus and

Salvia

5. The following additives that have CMR properties in unburned form:

a) substances classified as CMR according to Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, P. 1), as last amended by Regulation (EU) 2016/1179 (OJ L 195, 20.7.2016, p. 11). have been classified as CMR substances of category 1A, 1B or 2.

b) the following other substances:

Birch tar oil (CAS No. 8001-88-5 and CAS No. 85940-29-0).

juniper tar oil (CAS No. 8013-10-03)

Sassafras oil

Sassafras wood

Sassafras leaves

Sassafras bark

methyl eugenol (CAS No. 93-15-2)

Tarragol (CAS No. 140-67-0)

Para-hydroxybenzoic acid propyl ester (CAS No. 94-13-3)

*Based on a court decision heated tobacco products are to be classified as smokeless tobacco products. Therefore, the ban on additives that enhance inhalation do not apply.