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Betreft Input online consultatie Imperial Tobacco.

Via onderstaande antwoorden reageert Imperial Tobacco Nederland, namens de Imperial Tobacco Group (ITG) op een aantal specifieke punten met betrekking tot de online consultatie van het Rookwarenbesluit, zoals deze per 22 juli j.l. door de regering is gepubliceerd. Imperial is, als producent van zowel shag en pijptabak, sigaretten en sigaren een belangrijke speler binnen de Nederlandse tabaksindustrie. De wijzigingen en technische specificaties die worden voorgesteld in de Nederlandse Tabakswet, en die verder uitgewerkt zouden worden in deze AMvB hebben dan ook direct gevolgen voor de bedrijfsvoering van Imperial. Op basis van deze positie en de kennis van het speelveld heeft ITG, aanvullend op de inbreng van de Stichting Sigaretten Industrie (SSI) en de Vereniging Nederlandse Kerftabakindustrie (VNK) enkele op en aanmerkingen met betrekking tot de technische uitwerkingen van de thans ter consultatie voorliggende AMvB.

Doel van de regering
ITG kan zich vinden in het doel van de regering. Te weten, verdere implementatie van de Tabaksproductenrichtlijn, met als uitgangspunt een hoog niveau van bescherming van de volksgezondheid in het bijzonder voor jongeren. Juist vanwege deze doelstelling meent ITG nog enkele op en aanmerkingen te moeten plaatsen bij de voorliggende consultatie.

Vraag 1 van 7
In de huidige Nederlandse wetgeving zijn maximumemmissieniveaus vastgesteld voor emissies van teer, nicotine en koolmonoxide in sigaretten. Voor shagtabak is op dit moment alleen een maximumemissieniveau voor teer vastgesteld. Met dit conceptbesluit is ervoor gekozen om, in artikel 2.1, tweede lid, voor shagtabak ook maximumemissieniveaus vast te stellen voor de emissies van nicotine en koolmonoxide (artikel 3, derde lid, van de Tabaksproductenrichtlijn). Dit vermindert de schadelijkheid van het product en vergroot de uniformiteit tussen maximumemissieniveaus van verschillende tabaksproducten.

Bent u het hiermee eens? Zo ja, waarom wel? Zo nee, waarom niet?

Response ITG:
DISAGREE

We are aware of the current limit for tar in the smoke of rolling tobacco and all such products manufactured by Imperial Tobacco for sale in The Netherlands comply with it, and we would have no objection to continue to confirm compliance in all future submissions.

However, the rationale to introduce additional maximum emission levels (for both nicotine and carbon monoxide) as given in the question appears to be based on nothing than extending the requirements for cigarettes to rolling tobacco. This ignores a major difference between these two tobacco product categories: cigarettes are ready-to-use products that have a multitude of tools available during the design process to impact and steer emission levels, i.e. filter components. In contrast, rolling tobacco is a semi-finished product where emission levels depend on how the consumer chooses to make a smokeable article out of it (i.e. which paper, amount of tobacco, tightness of rolling).

Of particular relevance is that there is not necessarily a 10:1 relationship between tar and nicotine as this ratio highly depends on the tobacco types used in a rolling tobacco blend. Compared to cigarettes, blends of rolling tobacco utilise different tobacco types in certain product segments (i.e. in zware brands) where this ratio is around 9:1. A nicotine limit of 1.2 mg in combination with the existing 12 mg maximum limit for tar would unduly affect the well-established Zware brands in The Netherlands, distort the market and prevent product differentiation.

The second argument in the rationale claims that these additional maximum emission levels 'will reduce the harmfulness of the product'. This argument fails to understand that laboratory measurement methods which are used to determine emission levels are not suitable - and have never been intended - to evaluate exposure and nor are they appropriate as a basis for evaluating the potential harm of individual smokers. Instead, emission levels obtained under standard laboratory conditions using validated measurement methods are only designed to compare and rank individual brands.

We understand that further technical details, including specified measurement methods would become part of a future Ministerial Decree. Laboratory results for emissions of rolling tobacco show higher measurement variability compared to those obtained from factory-made cigarettes even when robustly developed and internationally validated measurement methods (i.e. ISO standards) are used. This is mainly caused by the (manual) making process for preparing test articles used in the laboratory process for analysing emissions of rolling tobacco.

Any measurement method specified in a regulation must have an established approach to interpret results obtained from it from measurements of the same product by different laboratories ('tolerances'), particularly when a maximum limit is set for it. The current practice regarding tar limits in The Netherlands has not yet established a robust process to define such 'tolerances'; instead, an unofficial approach to interpret results is applied by the authorities to check compliance with the maximum limit. Established 'tolerances' for all emissions where maximum limits are set allow a consistent interpretation should results from a governmental laboratory differ from those measured by a, for example, a laboratory from a manufacturer and would minimise disputes whether or not a product is compliant.

Imperial Tobacco welcomes the opportunity to engage further with the Dutch authorities on the proposed maximum emission levels (TPD Articles 3(3) and 4(4).

Vraag 2 van 7

De artikelen 9 en 10 van de Tabaksproductenrichtlijn bepalen verdergaande verpakkingseisen voor tabaksproducenten door een informatieve boodschap en gecombineerde gezondheidswaarschuwing op de verpakkingen te eisen. De gecombineerde gezondheidswaarschuwing bestaat uit een afschrikwekkende illustratie en tekst. De richtlijn geeft echter de keuzevrijheid aan lidstaten om andere voor roken bestemde tabaksproducten dan sigaretten, shagtabak en waterpijptabak vrij te stellen van de informatieve boodschap en de gecombineerde gezondheidswaarschuwing. In dit conceptbesluit is, in artikel 3.2, eerste lid, geen gebruik gemaakt van deze vrijstelling. Een gedifferentieerde aanpak ten aanzien van de verpakking van verschillende tabaksproducten kan namelijk onbedoeld de indruk wekken dat het ene product minder schadelijk voor de gezondheid is dan het andere. Dit moet worden voorkomen.

Bent u het hiermee eens? Zo ja, waarom wel? Zo nee, waarom niet?

Response ITG:

DISAGREE

EU BACKGROUND

- Considering EUTPD focus on young people, Cigars were exempted from Articles 9 and 10 in the original Commission proposal.
- Also the European Parliament was of the opinion that tobacco for smoking other than cigarettes and RYO should be exempted from the obligations to carry the Information Message laid down in article 9.2 and the combined health warnings in article 10.
- A change during the Trilogue Process of the expression "shall grant" to "may grant" impacted on article 11, causing a number of less appropriate, even unintended consequences for cigars, due to the fact that Articles 9 and 10 were not modified according to this fundamental change, and do not contain any reference to cigars.

TOBACCO PRODUCTS DIRECTIVE'S OBJECTIVES

- The objective of Directive 2014/40/EU is to approximate the laws, regulations and administrative provisions of the Member States concerning, among others, the ingredients, labelling and packaging of tobacco products.
- Public Health's protection level achieved with the tobacco Products Directive is very high and any additional measures to be adopted by the Dutch
  Regulator in relation to cigars would negatively impact on the cigar manufacturer's right to do business.
- Directive 2014/40/EU contains labelling rules that are specific for cigars, cigarillos and pipe tobacco (called "tobacco products for smoking, other than cigarettes and roll-your-own tobacco") and the labelling of these other tobacco products should follow rules that are specific to them".

SPECIFITIES OF THE CIGAR SECTOR

a) Cigar Consumer profile

The cigar consumer profile and portfolio characteristics need to be taken into account when regulating tobacco products. A "one size fits all approach" to tobacco regulation would not work as it would create a disproportionate burden for the cigar industry.

According to the data shown in the last Eurobarometer Report "Attitudes of Europeans towards tobacco and electronic cigarettes" issued by the European Commission in May 2015 the prevalence of cigar both in the EU and in the Dutch market, is very low and children and young people are not consumers of these products.
In that sense, consumption of cigars in the Netherlands is very low, with just 8% consumers using them on a daily, weekly or monthly basis (5% daily, 2% weekly, 1% monthly). Since 2012, there has been also a seven-point decline in the proportion of ex-smokers who have at least tried cigars in the Netherlands.

Regarding Youth usage, cigar consumption is also very low, with only 1% of 15-24 year-olds consuming these products on a daily, weekly or monthly basis at EU level.

b) Product characteristics

The enormous variety of models, sizes, brands, types of packaging (cardboard, metal, plastic, wood) and the small scale production processes make arts. 9 & 10 of the Directive 2014/40/EU difficult to implement. There is no machinery available that would make cigars compliant with Art. 9 & 10 and time to develop the machine, where it is possible, is around 12- 18 months.

TECHNICAL ISSUES

There are some technical issues that would impede to implement art. 9 & 10 in some variants of the cigar portfolio.

(i) Problems related to the Health Warning Size

There is no provision in art. 9 &10 regarding a "maximum size".
Many cigar boxes have areas greater than 150 cm2. Until now, and also according to art. 11 of the Directive 2014/40/EU, there are special provisions for these of boxes. However, art. 9 & 10 do not contain these special rules and if art. 11 is not granted boxes with a surface greater than 150 cm2 will have Health Warnings of 65% of the surface.
In case art. 11 is not granted Warnings in the cigar portfolio will be disproportionally dominant and that was not intention of the regulator.

(ii) Machinery restrictions

Due to the small production volumes of different variants the cigar industry does not print health warnings on the pack as it would not be cost efficient; for that reason stickers are allowed for cigars.

As Art. 9 & 10 were not designed for cigars they do not take into consideration machinery limitations in relation to the use of stickers. Please see below, amongst others, the most relevant examples of machinery limitations on the cigar portfolio:

a) Machine Made cigars tend to use "shoulder box" formats where laterals split in two when the pack opens. If art. 9 & 10 are applied to these cigar formats the height of the lateral will be very small and no existing machine will be able to sticker on these small surfaces; from a practical perspective stickers will need to be applied manually.

   If the Dutch Regulator applies art. 9 & 10 to "shoulder box formats" and new machinery needs to be developed there is the risk that manufacturers cannot comply with the new requirements due to cost and also timing as they will need 12-18 months to have machinery in place.

b) Arts. 9 & 10 cannot be implemented on cigar tubes. Surface suggested (65% front and back and 50% on each lateral) make it impossible for manufacturers to comply in relation to cigar tubes.

In view of the above ITG suggests excluding tubes from the current regulation.

JUSTIFICATION

Article 11 of Directive 2014/40/EU contains specific labelling rules for cigars, cigarillos and pipe tobacco referred to in recital 26, and these standards are much tougher than the current ones. Pursuant to the above and in order to achieve the objective of an EU internal market harmonized for cigars, cigarillos and pipe tobacco, ITG strongly urge the Dutch national authorities to implement specific labelling rules laid down in article 11 of the Directive for these types of products.

POTENTIAL CONSEQUENCES FOR THE CIGAR SECTOR IF ART. 11 EXEMPTION IS NOT GRANTED

If the exemption contained in art. 11 is not granted for cigars, cigarillos and pipe tobacco there is the risk that two different labelling regimes coexist within the EU (as other EU member states will grant the exemption) and EU internal market could suffer disruptions plus the purpose of the Directive, which is the approximation of legislative and regulatory provisions within the EU, would not be met.

In addition, the co-existence of two systems of labelling for cigars, cigarillos and pipe tobacco would impact on production processes because it requires two types of machines – one for each labelling system – at greatly increased cost and complexity for the manufacturers.

Therefore the cigar industry would suffer disproportionately, especially the small and medium enterprises (i.e. severe economic consequences and the elimination of certain formats because of the technical impossibility to adapt the cigar labelling processes to the requirements of the labelling of cigarettes).

Vraag 3 van 7

De Tabaksproductenrichtlijn stelt diverse rapportageverplichtingen aan producenten en importeurs van tabaksproducten en elektronische sigaretten. Daarnaast geeft artikel 6, vierde lid, van de Tabaksproductenrichtlijn ruimte aan lidstaten om aanvullende informatie te vragen. Met dit conceptbesluit worden vooralsnog geen aanvullende rapportageverplichtingen opgelegd aan producenten en importeurs, bovenop de gegevens die producenten en importeurs al moeten verstrekken op grond van de Tabaksproductenrichtlijn. Pas als blijkt dat aanvullende informatie noodzakelijk is en de gegevens ook doeltreffend door de bevoegde autoriteit kunnen worden verwerkt, zal van deze beleidskeuze gebruik worden gemaakt.

Bent u het hiermee eens? Zo ja, waarom wel? Zo nee, waarom niet?

Response ITG:

AGREE

We understand that reporting requirement for tobacco products and electronic cigarettes are either described in detail by the EU Directive or are subject to secondary legislation derived from it. Imperial Tobacco welcomes the opportunity to engage further with the Dutch authorities on the proposed common reporting format for ingredients and emissions data of tobacco products and e-cigarettes (TPD Articles 5(5) and 20(13)).

Vraag 4 van 7
In het voorgestelde artikel 4.3, derde lid, van het conceptbesluit wordt bepaald dat verslagen over additieven, die door producenten van sigaretten en shagtabak moeten worden ingediend, worden beoordeeld door een onafhankelijke wetenschappelijke instantie (artikel 6, vierde lid, van de Tabaksproductenrichtlijn). Hier wordt gebruik van gemaakt, zodat de verslagen objectief worden beoordeeld.

Bent u het hiermee eens? Zo ja, waarom wel? Zo nee, waarom niet?

Response ITG:
DISAGREE

Peer review is appropriate for certain types of evidence, including some that may be submitted as part of an evidence package, but it is not an appropriate procedure for all of the data that will be provided. For example, if manufacturers undertake to perform a joint study supporting the use of certain priority additives, it may be appropriate to submit such a study for peer review.

However, it is foreseeable that much of the evidence may already be available from the published literature, in which case it will have been subject to a peer review process already. Other evidence will be submitted in the form of data, in which case having an agreed format could be beneficial. It would also be appropriate for the data provided to be authenticated through the use of accredited laboratories (e.g. the Dutch accreditation body or respective ones in other MS).

Secondly, as Article 6 TPD specifies that the priority list will be established by the European Commission (the Commission) under implementing acts it would be appropriate for the studies to be co-ordinated through the Commission as well as the peer review to avoid duplication and different approaches/criteria being applied. This is especially relevant given that the draft implementing act for data reporting under Article 5 of the Directive also establishing a centralised procedure.

Finally to enable a peer review of any joint study to be properly conducted would take considerably longer than the 18 months specified in Article 6(4), and for that reason member states should refrain from making it an absolute requirement.

Imperial Tobacco welcomes the opportunity to engage further with the Dutch authorities on the proposed common reporting format for ingredients and emissions data of tobacco products and e-cigarettes (TPD Articles 5(5) and 20(13)) and the list of priority additives for which enhanced reporting obligations shall apply (TPD Article 6(1)).
