



Joint Action on Tobacco Control (JATC)
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WP7 – D7.2 “Checklist for e-cigarette product compliance to the TPD”

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Introduction

The EU Tobacco Products Directive (TPD) 2014/40/ EU9 along with Commission Implementing Decisions EU 2016/586 (2016)¹⁰ and EU 2015/2183 (2015)¹¹, has established standards for e-cigarette reporting, product safety and packaging. Specifically, the provisions of EU TPD Article 20 enumerate product labelling, packaging, composition and technical requirements including, but not limited to, child-resistant packaging features, refill container volume, nicotine content levels, health warning labels, informational leaflets, and technical parameters to reduce the risk of spilling during refill or leaking during use.

The overall objective of this specific Work Package (WP) is to support the activities of the EU MS in ensuring that electronic cigarettes and refill containers are placed on the market in compliance with the TPD. Specific objectives include the performance of a needs assessment of EU MS regulators with regards to e-cigarette product evaluation through EU-CEG, an assessment of e-cigarette data submitted via the EU-CEG, the monitoring of reported e-cigarette liquid ingredient and emission data in line with TPD Art20(2) and the creation of a checklist for e-cigarette product compliance to the TPD and develop a reporting format for adverse effects on human health.

This deliverable (D7.2) presents a clear and comprehensive checklist in the form of an Xls file, which was created by WP7, to facilitate the monitoring of e-cigarette product compliance to the TPD (both for manufacturers and regulators) under the auspices of TPD Art20(1) and including, but not limited, to Art20(3-4) and implementing act 2016/586.

Checklist for e-cigarette product compliance to the TPD

| Information about inspection | | | |
|-----------------------------------|--|-----------------------------|------------|
| Date: | | | |
| Time: | | | |
| Inspection Type: | | | |
| Inspecting Officer(s): | | | |
| Contact Person: | | | |
| Position/Title: | | | |
| Additional information: | | | |
| General information about company | | | |
| Name: | | | |
| Registration No: | | | |
| Address: | | | |
| Contact number, e-mail: | | | |
| Business Type: | | | |
| Product Type: | | | |
| Additional information: | | | |
| Product description | | | |
| 1 | | | |
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| 3 | | | |
| 4 | | | |
| 5 | | | |
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| Product Assessment | | Legislative act and Article | Compliance |
| 1 | The notification is submitted in electronic form six months before the intended placing on the market | TPD 20.2. | |
| 2 | Manufacturers, importers and distributors of electronic cigarettes and refill containers has established and maintain a system for collecting information about all of the suspected adverse effects on human health of these products | TPD 20.9. | |
| Comment: | | | |

| Labelling | | Legislative act and Article | Compliance |
|-----------|---|-----------------------------|------------|
| 3 | Unit packets of electronic cigarettes and refill containers carries one of the following health warnings in the official language of the Member State where the substance or mixture is placed on the market: | TPD 20.4.b.iii | |
| 3,1 | 'This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers' | TPD 20.4.b.iii | |
| 3,2 | 'This product contains nicotine which is a highly addictive substance' | TPD 20.4.b.iii | |
| 4 | The health warning comply with the requirements: | TPD 20.4.c | |
| 4,1 | it appears on the two largest surfaces of the unit packet and any outside packaging | TPD 12.2.a | |
| 4,2 | it is printed in black Helvetica bold type on a white background and occupies the greatest possible surface reserved for the health warning | TPD 9.4.a | |
| 4,3 | it is placed at the centre of the surface reserved for them | TPD 9.4.b | |
| 4,4 | on cuboid packets and any outside packaging it is parallel to the lateral edge of the unit packet or of the outside packaging | TPD 9.4.b | |
| 4,5 | it covers 30 % of the surfaces of the unit packet and any outside packaging (Proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with more than two official languages) | TPD 12.2.b | |
| 4,6 | the health warnings may be affixed by means of stickers, provided that such stickers are irremovable. The health warnings shall in no way hide or interrupt the tax stamps, price marks, tracking and tracing marks, or security features on unit packets. Health warnings shall be surrounded by a black border of a width of 1 mm inside the surface area that is reserved for these warnings | TPD 8.3, 8.4, 8.6. | |
| 5 | Unit packets and any outside packaging of electronic cigarettes and refill containers: | TPD 20.4.b | |
| 5,1 | include a list of all ingredients contained in the product | TPD 20.4.b.i | |
| 5,2 | a list of all ingredients contained in the product is in descending order of the weight | TPD 20.4.b.i | |
| 5,3 | include an indication of the nicotine content of the product and the delivery per dose | TPD 20.4.b.i | |
| 5,4 | include the batch number | TPD 20.4.b.i | |
| 5,5 | include a recommendation to keep the product out of reach of children | TPD 20.4.b.i | |
| 6 | Unit packets of electronic cigarettes and refill containers include a leaflet with information on: | TPD 20.4.a | |
| 6,1 | instructions for use and storage of the product, including a reference that the product is not recommended for use by young people and non-smokers | TPD 20.4.a.i | |
| 6,2 | contra-indications | TPD 20.4.a.ii | |
| 6,3 | warnings for specific risk groups | TPD 20.4.a.iii | |
| 6,4 | possible adverse effects | TPD 20.4.a.iv | |

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| 6,5 | addictiveness and toxicity | TPD 20.4.a.v | |
| 6,6 | contact details of the manufacturer or importer and a legal or natural contact person within the Union | TPD 20.4.a.vi | |
| 7 | Refillable electronic cigarettes and refill containers include appropriate instructions for refilling, including diagrams | DECISION 2016/586 2.2. | |
| 8 | The labelling of unit packets and any outside packaging and the electronic cigarettes and refill containers itself do not include any element or feature that: | TPD 13.1. | |
| 8,1 | promotes a product or encourages its consumption by creating an erroneous impression about its characteristics, health effects, risks or emissions | TPD 13.1.a | |
| 8,2 | suggests that a particular product is less harmful than others or has vitalising, energetic, healing, rejuvenating, natural, organic properties or has other health or lifestyle benefits | TPD 13.1.b | |
| 8,3 | makes any reference to the taste or smell of an electronic cigarette or refill container | TPD 13.1.c | |
| 8,4 | resembles a food or a cosmetic product | TPD 13.1.d | |
| 8,5 | suggests that a certain product has improved biodegradability or other environmental advantages | TPD 13.1.e | |
| 9 | The unit packets and any outside packaging do not suggest economic advantages by including printed vouchers, offering discounts, free distribution, two-for-one or other similar offers | TPD 13.2. | |
| 10 | The labeling contains information about the nominal quantity of the mixture in the package | CLP 1272/2008 17.1.b | |
| 11 | Nicotine-containing liquid is classified in accordance with legislation | CLP 1272/2008 3., 4., 5., 6., 9., 10., 11., 12., 13., 14., 15., Annex I | |
| 12 | In accordance with classification nicotine-containing liquid package labeling includes: | | |
| 12,1 | If the nicotine-containing liquid is placed on the market in refill container, cartridges or tanks without outside packaging refill container, cartridges or tanks labeling includes: | | |
| 12.1.1 | hazard pictograms | CLP 1272/2008 17.1.d, 19., 31.4. | |
| 12.1.2 | signal words | CLP 1272/2008 17.1.e, 20. | |
| 12.1.3 | hazard statements | CLP 1272/2008 17.1.f, 21. | |
| 12.1.4 | precautionary statements | CLP 1272/2008 17.1.g, 22. | |

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| 12.1.5 | product identifier | CLP 1272/2008 17.1.c, 18. | |
| 12.1.6 | name and contact information of the supplier | CLP 1272/2008 17.1.a | |
| 12,2 | If the nicotine-containing liquids refill container, cartridges or tanks is placed on the market with outside packaging | | |
| 12.2.1 | Refill container, cartridges or tanks labeling includes: | | |
| 12.2.1.1 | hazard pictograms | CLP 1272/2008 17.1.d, 19., 31.4. | |
| 12.2.1.2 | product identifier | CLP 1272/2008 17.1.c, 18. | |
| 12.2.1.3 | name and contact information of the supplier | CLP 1272/2008 17.1.a | |
| 12.2.2 | Outside packaging labeling includes: | | |
| 12.2.2.1 | hazard pictograms | CLP 1272/2008 17.1.d, 19., 31.4. | |
| 12.2.2.2 | signal words | CLP 1272/2008 17.1.e, 20. | |
| 12.2.2.3 | hazard statements | CLP 1272/2008 17.1.f, 21. | |
| 12.2.2.4 | precautionary statements | CLP 1272/2008 17.1.g, 22. | |
| 12.1.5 | product identifier | CLP 1272/2008 17.1.c, 18. | |
| 12.1.6 | name and contact information of the supplier | CLP 1272/2008 17.1.a | |
| 13 | Nicotine-containing liquid package (refill container, cartridges, tanks, outside packaging) need to be fitted with a tactile warning of danger | CLP 1272/2008 Annex II 3.2. | |
| Comment: | | | |
| Packaging | | Legislative act and Article | Compliance |
| 14 | Nicotine-containing liquid is only placed on the market in: | TPD 20.3.a | |
| 14,1 | dedicated refill containers not exceeding a volume of 10 ml | TPD 20.3.a | |

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| 14,2 | disposable electronic cigarettes or in single use cartridges and that the cartridges or tanks do not exceed a volume of 2 ml | TPD 20.3.a | |
| 15 | Electronic cigarettes and refill containers are child- and tamper-proof, are protected against breakage and leakage and have a mechanism that ensures refilling without leakage | TPD 20.3.g CLP 1272/2008 35.2. second part | |
| Comment: | | | |
| Composition | | Legislative act and Article | Compliance |
| 16 | The nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml | TPD 20.3.b | |
| 17 | The nicotine-containing liquid does not contain: | TPD 20.3.c | |
| 17,1 | vitamins or other additives that create the impression that electronic cigarettes and refill containers has a health benefit or presents reduced health risks | TPD 7.6.a | |
| 17,2 | caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality | TPD 7.6.b | |
| 17,3 | additives having colouring properties for emissions | TPD 7.6.c | |
| 17,4 | additives that facilitate inhalation or nicotine uptake | TPD 7.6.d | |
| 17,5 | additives that have CMR properties | TPD 7.6.e | |
| 18 | Only ingredients of high purity are used in the manufacture of the nicotine-containing liquid. Substances other than the ingredients referred to in point (b) of the second subparagraph of paragraph 2 of this Article are only present in the nicotine-containing liquid in trace levels, if such traces are technically unavoidable during manufacture | TPD 20.3.d | |
| 19 | Only ingredients are used in the nicotine-containing liquid that do not pose a risk to human health in heated or unheated form | TPD 20.3.e | |
| Comment: | | | |
| Technical requirements for electronic cigarette and refill mechanism | | Legislative act and Article | Compliance |
| 20 | Electronic cigarettes deliver the nicotine doses at consistent levels under normal conditions of use | TPD 20.3.f | |
| 21 | Refillable electronic cigarettes and refill containers are only placed on the market if the mechanism by which the electronic cigarettes are refilled meets one of the following conditions: | DECISION 2016/586 2.1 | |
| 21,1 | it entails the use of a refill container possessing a securely attached nozzle at least 9 mm long, which is narrower than and slots comfortably into the opening of the tank of the electronic cigarette with which it is used and possessing a flow control mechanism that emits no more than 20 drops of refill liquid per minute when placed vertically and subjected to atmospheric pressure alone at 20 °C ± 5 °C; indicate the | DECISION 2016/586 2.1.a, 2.2. | |

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| | width of the nozzle or width of the opening of the tank in the instructions for use in a manner that enables consumers to identify the compatibility of refill containers and electronic cigarettes | | |
| 21,2 | it operates by means of a docking system which only releases refill liquids into the tank of the electronic cigarette when the electronic cigarette and refill container are connected; in the instructions for use, the types of docking system with which such electronic cigarettes and refill containers are compatible | DECISION 2016/586 2.1.b, 2.2. | |
| Comment: | | | |
| Material safety data sheet (REACH) | | Legislative act and Article | Compliance |
| 22 | Safety data sheet is available if nicotine-containing liquid meets the criteria for classification as hazardous in accordance with CLP 1272/2008 | REACH 1907/2006 31.1., 31.3. | |
| 23 | The safety data sheet is in an official language of the Member State where the substance or mixture is placed on the market | REACH 1907/2006 31.5. | |
| 24 | The safety data sheet is compliant with legislative acts | REACH 1907/2006 31.1., 31.6., Annex II | |
| 25 | Based on the classification elements appearing on the label are the same that are indicated in article 2.2. of safety data sheet | REACH 1907/2006 Annex II 2.2. | |
| Comment: | | | |
| Inspection Outcome | | | |
| Comment: | | | |