REPORT ON THE 9TH JOINT CROSS-BORDER EMC MARKET SURVEILLANCE CAMPAIGN (2017)

E-cigarettes

Final

Contents

A. Executive summary

As a result of discussions at the 41th EMC Administrative Cooperation Working Group (EMC ADCO) agreed that the ninth joint cross-border EMC market surveillance campaign (MSC-EMC-09) will assess the compliance of e-cigarettes. Global use of e-cigarettes has risen exponentially and the products have spread to the EU market quickly and widely.

This report provides an overview of the campaign and findings, and makes recommendations on next steps and future actions.

The primary purpose of the campaign was to assess the formal compliance of the e-cigarettes, samples taken from the European market, with the administrative requirements of the EMC Directives 2004/108/EC or 2014/30/EU. The campaign was planned to last 6 months and it started on the 1st of January 2017.

During the first 4 months (January-April) samples were selected and the administrative requirements were assessed. Administrative compliance will be checked against

- CE marking,
- Declaration of Conformity ('DoC'),
- Traceability (name or registered trademark and address of the manufacturer/importer)

Other marking requirements and Technical Documentation ('TD') were assessed on a voluntary basis. Also technical compliance of e-cigarettes was assessed on a voluntary basis.

Ten national Market Surveillance Authorities ('MSA') EMC ADCO members participated in the campaign, 76 products were assessed between the 1st January 2017 and the 30th June 2017.

Based on this campaign EMC ADCO has formulated conclusions and recommendations which can be found in Chapter D of this report.

The results of the administrative assessment of e-cigarettes showed:

- Approximately one third (36%) of the products were formally compliant.
- Three products were not CE marked, 68 (89 %) were assessed as meeting the correct formatting requirements.
- Declarations of Conformity (DoC) were available for 50 products, from those, 37 were compliant (50 % overall DoC compliance).
- From 21 requested TD 16 (76 %) were made available. From those, 10 were compliant (48 % overall TD compliance).

16 e-cigarettes were assessed technically, all products were compliant to assessed technical requirements.

B. Elements of the Campaign

1. Introduction

An electronic cigarette or e-cigarette is a battery-powered handheld electronic device that vaporizes a flavoured liquid, which the user inhales. The fluid in the e-cigarette, called e-liquid, usually includes nicotine and propylene glycol, as well as flavourings and other chemicals. Some e-cigarettes contain no nicotine.

During use, inhalation activates a pressure-sensitive circuit that heats the atomizer and turns the liquid into an aerosol that is inhaled by the user through the mouthpiece and exhaled as a fine mist. Some e-cigarettes have buttons that allow the user to manually activate the heating element.

The first modern e-cigarette was invented in 2003 by Chinese pharmacist and also today most e-cigarettes are made in China. Global use has risen exponentially, although the health risks of e-cigarettes are uncertain. While they are likely safer than tobacco cigarettes, the long-term health effects are not known.

E-cigarettes are usually approximately cylindrical, with many variations: pen-styles, tank-styles etc. Some e-cigarettes look like traditional cigarettes, but others do not. There are three main types of e-cigarettes: cigalikes, looking like cigarettes; eGos, bigger than cigalikes with refillable liquid tanks; and mods, assembled from basic parts or by altering existing products.

Fig.1. Examples of different e-cigarettes

The primary parts that make up an e-cigarette are a mouthpiece, a cartridge (tank), a heating element/atomizer, a rechargeable battery and possibly a LED light on the end. The battery is the largest component of an electronic cigarette. Most e-cigarettes have lithium ion battery. Battery life depends on type, size, the number of using and operating environment. There are many different types of battery chargers to choose, such as mains powered charger, car charger and USB charger.

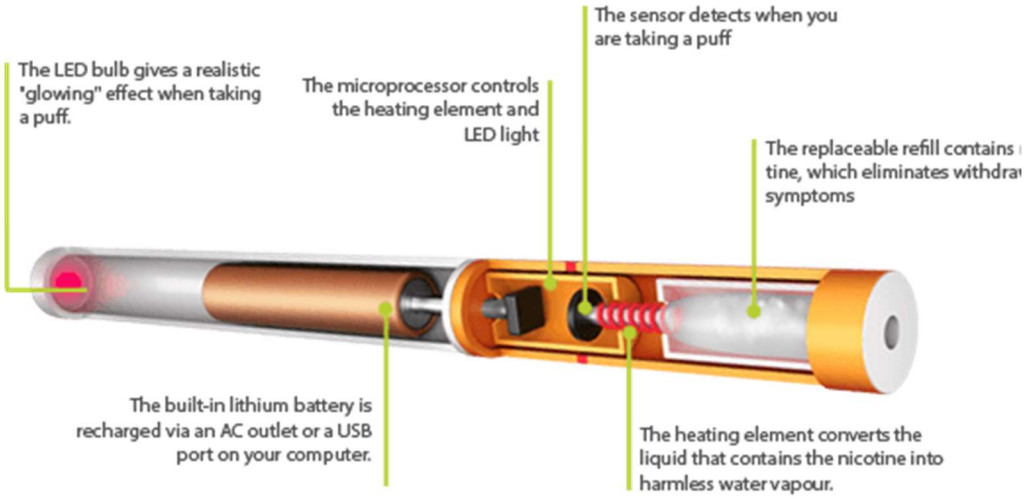

Fig.2. Construction of an e-cigarette

2. Reasons for the campaign

As a result of discussions at the 41th EMC Administrative Cooperation Working Group (EMC ADCO) agreed that the ninth joint cross-border EMC market surveillance campaign (MSC-EMC-09) will assess the compliance of e-cigarettes. Global use of e-cigarettes has risen exponentially and the products have spread to the EU market quickly and widely.

3. Scope of the campaign

The primary purpose of the campaign was to assess the formal compliance of the e-cigarettes, samples taken from the European market, with the administrative requirements of the EMC Directives 2004/108/EC or 2014/30/EU.

Formal compliance was checked against

- CE marking,
- Declaration of Conformity ('DoC'),
- Traceability (name or registered trademark and address of the manufacturer/importer)

Other marking requirements and Technical Documentation ('TD') were assessed on a voluntary basis. Also technical compliance of e-cigarettes was assessed on a voluntary basis.

The campaign was also intended to provide MSA with the opportunity to participate in EMC market surveillance, to improve the exchange of information and to raise economic operator and consumer's awareness of the need for conformity with the requirements of the EMC Directive.

It was agreed that following the analysis of the results of the campaign, a report would be prepared and presented to the EMC Working Party for subsequent publication by the Commission. The present document constitutes the report of the campaign.

4. Participation in the campaign

Participation in the campaign was voluntary, and was open to all members of EMC ADCO. Each MSA was responsible for the costs of purchasing and testing the products.

Ten European countries participated in the campaign: Croatia, Estonia, Germany, Hungary, Iceland, Lithuania, Poland, Romania, The Netherlands and the United Kingdom.

5. Timing

The campaign was planned to last 6 months and it commenced on the 1st of January 2017. During the first 4 months samples were selected and the administrative requirements (DoC, instructions and markings) were assessed. The obtained results of administrative assessment were evaluated and filled in the DIFs.

During the last 2 months (May-June) all results of administrative assessment were collected together and the final report of the joint action was prepared. MSA also carried out national enforcement measures (if necessary).

6. Sampling

The aim was to obtain the broadest possible view of the investigated product group in the European marketplace. Therefore, a quasi-random sampling was performed over the whole price range, and from all origins (national, EEA, and imported from third countries). However, to avoid double sampling, each participating MSA was encouraged to upload details of its selections into ICSMS as early in the course of campaign as possible.

7. Documents

A Code of Practice was drawn up to provide guidance and a common understanding of the purpose of the campaign and to ensure, as far as possible, the adoption of harmonised practices during the carrying out of the campaign.

The results of the assessment of each product were recorded on a common electronic data input form for EMC (EMC DIF).

8. Testing

Technical compliance was assessed on a voluntary basis.

The emission measurements were carried out in accordance with generic standard EN 61000-6-3:2007 + A1:2011. The immunity measurements were carried out in accordance with generic standard EN 61000-6-1:2007.

If MSA decided to perform technical compliance assessment, it was recommended to perform:
- immunity to electrostatic discharge test according to EN 61000-6-1:2007 for e-cigarettes (enclosure port);
- conducted emissions in 0.15 MHz to 30 MHz frequency range test according to EN 61000-6-3:2007 + A1:2011 of mains powered charger (if included) (low voltage AC mains port).

C. Results

Administrative compliance was checked against traceability (identification markings (type, batch or serial number) and name or registered trademark and address of the manufacturer/importer), the presence and format of CE marking, the availability and compliance of the EU Declaration of Conformity (DoC) and technical documentation (TD).

A total of seventy-six (76) products were assessed, 36 % of those fulfilled the assessed administrative requirements.

Compliance with formal requirements		
Number of assessed e-cigarettes	Number of compliant e-cigarettes	Compliance (%)
76	27	36

1. Country of origin (Made in…)

MSA had to report on the country where the product has been manufactured; the information "Made in" present either on the products itself, on its packaging or on the accompanying documents and finally from the DoC (where available). The "country of origin" therefore refers not generally to the economic operator who is responsible for placing the product on the EU market.

A total of seventy-six (76) products were selected and evaluated, as follows

Country of origin	Number of assessed e-cigarettes	Compliance level of assessed formal requirements
China	63	24 (38 %)
Malaysia	2	2 (100 %)
EU	1	0 (0 %)
Unknown	10	1 (10 %)
All origins	76	27 (36 %)

Most of the products have been manufactured in China (83 %) or country of origin is unknown (13 %). Only one product was manufactured in Europe.

When analysing the results, it was recognised a strong correlation between when country of origin was unknown and poor compliance level of assessed administrative requirements. Only one product with unknown origin was compliant with assessed administrative requirements.

2. Traceability Requirements

Manufacturers shall ensure that products which they have placed on the market bear a type, batch or serial number or other element allowing its identification. Manufacturers and importers (if manufacturer is not established in the EU) shall indicate, on the product, their name, registered trade name or registered trade mark and the postal address at which they can be contacted.

A total of seventy-six (76) products were assessed, as follows

Compliance of traceability requirements		
Requirement of traceability	Number of compliant e-cigarettes	Compliance (%)
Identification requirements	74	97
Name of the manufacturer	61	80
Address of the manufacturer	57	75
Name of the importer	36*	65
Address of the importer	36*	65

* In 21 cases the information of importer was not required, because the manufacturer is established in the EU.

According to the assessed results the name and address of the manufacturer has been indicated better than the name and address of importer.

3. CE marking

Three assessed e-cigarettes were not CE marked, 5 did not fulfilled the formatting requirements and 60 products (88 %) were assessed as compliant.

Compliance with CE marking requirements					
Number of assessed e-cigarettes	Missing CE mark	Not compliant CE mark layout	Not compliant height of CE mark	Number of compliant CE mark	Compliance (%)
76	3	4	5	68	89

4. EU Declarations of Conformity (DoC)

MSA assessed 74 e-cigarettes against the DoC requirements. From 74 requested DoC 50 (68 %) were made available. From those 50 available, 37 were compliant, this represents 50 % overall DoC compliance.

Compliance with DoC requirements				
Number of assessed e-cigarettes	DoC available	DoC available (%)	Number of compliant DoC	Overall DoC compliance (%)
74	50	68	37	50

Compliance rate of the DoC requirements	
Requirements for DoC	Compliance rate for 50 DoC (%)
Reference to EMCD	98
Identification of the apparatus	90
Name and address of the manufacturer	94
Dated reference to the specifications	83
Date of declaration	88
Identity of the person empowered to bind the manufacturer	82
Signature of the person empowered to bind the manufacturer	88

5. Technical documentation (TD)

MSA assessed 21 e-cigarettes against the TD requirements. From 21 requested TD 16 (76 %) were made available. From those 16 available, 10 were compliant, this represents 48 % overall TD compliance.

Compliance with TD requirements*				
Number of assessed e-cigarettes	TD available	TD available (%)	Number of compliant TD	Overall TD compliance (%)
21	16	76	10	48

* Assessed TD requirements:

- General description of the products
- Evidence of compliance with harmonised standards (applied in full)
- Evidence of compliance with harmonised standards (applied in part)
- Description and explanation of the steps taken to meet the essential requirements of the directive (if manufacturer has not applied HS or has applied them only in part)
- Results of design calculations made, examinations carried out, test reports
- Statement from the notified body (if used)

6. Technical requirements

Emissions requirements

The emission measurements were carried out in accordance with generic standard EN 61000-6-3:2007 + A1:2011. The measured result was compared directly with the limit in the harmonised standard without taking into account the measurement uncertainty. A failure was recorded if any emission exceeded a certain limit when measured with the appropriate detector.

14 e-cigarettes were assessed against emissions requirements, all products were compliant with the assessed requirements.

Compliance with emissions requirements		
Number of assessed e-cigarettes	Number of compliant e-cigarettes	Compliance (%)
14	14	100

Immunity requirements

The immunity measurements were carried out in accordance with generic standard EN 61000-6-1:2007. 8 e-cigarettes were assessed against immunity requirements, all products were compliant with the assessed requirements.

Compliance with immunity requirements (ESD)		
Number of assessed e-cigarettes	Number of compliant e-cigarettes	Compliance (%)
8	8	100

D. Conclusion and Recommendations

1. Conclusion

- E-cigarettes were mainly of Chinese and unknown origin.
- Approximately one third (36%) of the products were formally compliant.
- Three products were not CE marked, 5 CE makings were incorrectly formatted and 60 (89 %) were CE marked correctly.
- Declarations of Conformity (DoC) were available for 50 products, from those, 37 were compliant (50 % overall DoC compliance).
- From 21 requested TD 16 (76 %) were made available. From those, 10 were compliant (48 % overall TD compliance)
- 16 e-cigarettes were assessed technically, all products were compliant to assessed technical requirements.
- The use of ICSMS for sampling and information gathering was found to be very helpful. The role of ICSMS for the MS work has been emphasized during the execution of the campaign.
- The project increased the awareness of the economic operators concerned on the requirements of EU harmonization legislation for the e-cigarettes. Many shortcomings in administrative requirements were due to a lack of information.

2. Recommendations

- The results of the project should be published widely throughout Europe. Publicity should target all economic operators in the area of e-cigarette industry in order to increase the knowledge of the EMC Directive.
- The results should also be actively disseminated to all responsible economic operators via various communication channels.
- European market surveillance authorities should take the results of this project into consideration when making their multi annual market surveillance plans as stated in the Regulation (EC) 765/2008.
- A similar campaign should be considered on the same basis after a certain period to assess the effect of this project on the European market.
- Market surveillance authorities should increase the usage of ICSMS for exchange of information.
- Market surveillance actions for e-cigarettes should be continued.