EN

European Commission

CASP2021

Coordinated Activities on the Safety of Products

E-cigarettes and liquids Final Report

Justice and Consumers

Table of contents

List of abbreviations

ABBREVIATION	DESCRIPTION
CASP	Coordinated Activities on the Safety of Products
CEN	European Committee for Standardization
CLP Regulation	Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures
DG JUST	Directorate-General for Justice and Consumers of the European Commission
EEA	European Economic Area
EISMEA	European Innovation Council and SMEs Executive Agency
EN	European Standard
EO	Economic operator
EU	European Union
GPSD	General Product Safety Directive (2001/95/EC)
ISO	International Organization for Standardization
KoM	Kick-off meeting
MS	Member State(s)
MSA	Market surveillance authority
PSA	Product-specific activity
RAG	Risk Assessment Guidelines
RAPEX Guidelines	Decision (EU) 2019/417
Safety Gate	Rapid alert system for dangerous non-food products
TPD	Tobacco Products Directive (2014/40/EU)
TS	Technical specification

Executive summary

Objectives of the activity

The Coordinated Activities on the Safety of Products (CASP) projects enable all the market surveillance authorities (MSAs) from European Union (EU) / European Economic Area (EEA) countries to cooperate in reinforcing the safety of products placed on the European Single Market. This activity focused on e-cigarette devices and e-liquids. The products were sampled and tested following commonly agreed criteria in a European laboratory selected by the participating MSAs.

Product scope

E-cigarette devices (single-use e-cigarettes, rechargeable e-cigarette devices of different sizes) and e-liquids with and without nicotine.

Main testing criteria

- CEN/TS 17287:2019 Requirements and test methods for electronic cigarette devices;
- ISO 13127:2012 Child resistant packaging – Mechanical test methods for re-closable child resistant packaging systems;
- emissions from e-cigarette devices;
- ISO 20714:2019 E-liquid – Determination of nicotine, propylene glycol and glycerol in liquids used in electronic nicotine delivery devices – Gas chromatographic method.

Results

- Number of products tested – 169:
  - 132 e-liquids;
  - 37 e-cigarette devices.
- A total of 137 samples (81%) met the requirements of the testing plan.
- A total of 32 samples (19%) did not meet at least one of the requirements of the testing plan:
- 22 e-cigarette devices (60%) and 10 samples of e-liquids (8%).

Key recommendations

For consumers

- Pay particular attention to warnings and markings, and carefully follow the instructions.
- Report any safety problems that arise when using a product and keep yourself informed about recall actions.

For economic operators (EOs)

- Be aware of your obligations under the applicable legislation.
- Perform regular controls on your products.
- Clearly communicate with consumers about recalls.

Conclusions

One out of five of the tested samples did not meet the relevant requirements. More than half of the samples did not meet the formal requirements on warnings, markings and instructions.

Risk assessments performed by the MSAs showed that one sample presented a serious risk and three presented a medium risk.

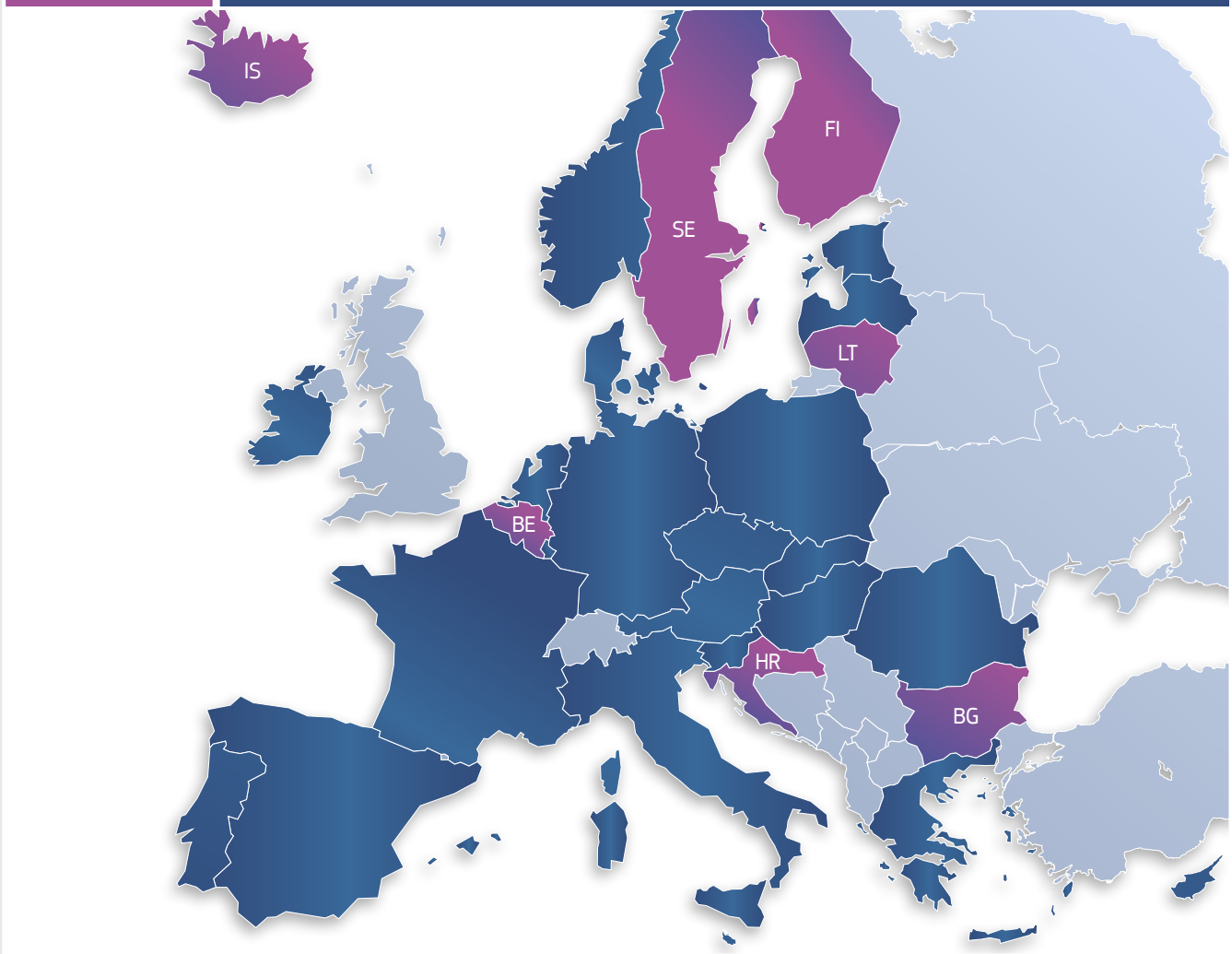
Among the main measures taken regarding products that did not meet the requirements, one product was recalled from the market and 15 were withdrawn.

1. Overview of the activity

1.1 Participating MSAs

A total of eight MSAs from six EU Member States (MS) and one EEA country participated in the E-cigarettes and liquids product-specific activity (PSA), as illustrated in the image below.

COUNTRY	MSA
Belgium	Federal Public Service Health, Food Chain Safety & Environment – Federal Environment Inspectorate
	Federal Public Service Economy – Directorate-General for Quality and Safety
Bulgaria	Commission for Consumer Protection
Croatia	State Inspectorate
Finland	National Supervisory Authority for Welfare and Health
Iceland	Housing and Construction Authority
Lithuania	State Consumer Rights Protection Authority
Sweden	Swedish National Electrical Safety Board



1.2 Product scope and testing criteria

1.2.1 Product scope

Table 1 - **Product scope**

E-CIGARETTE DEVICES	E-LIQUIDS

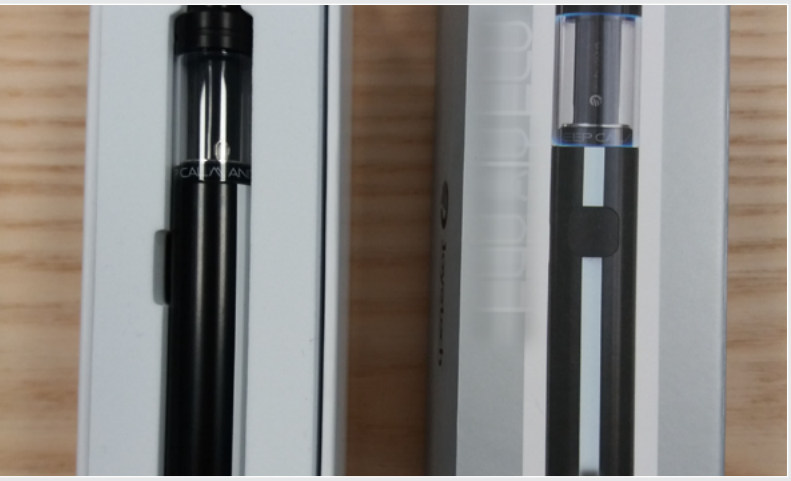
• Single-use e-cigarettes
• Rechargeable e-cigarette devices
  • sold as a single unit (excluding advanced personal vapourisers) designed to be refilled from bottles
  • with their own proprietary refill system, 'vape-pods'
	E-liquids with and without nicotine

1.2.2 Testing criteria

The testing plan for this activity was based on the requirements of the standards ISO 20714:2019, CEN/TS 17287:2019, and ISO 13127:2012 as well as criteria established in additional tests. The plan included assessments to verify the:

- chemical composition of the e-liquid, including the nicotine content;
- functionality and functional safety of the e-cigarette devices;
- child resistance and resistance to leakage (particularly during refilling) of the electronic cigarette devices;
- for some of the samples also the constituents of the aerosols used.

In addition to the laboratory tests, the MSAs also checked the accompanying warnings, markings and instructions in their national languages. A checklist with the main requirements was prepared by the technical expert to provide additional guidance for the MSAs.



2. Sampling and testing

2.1 Sampling distribution

The sampling was carried out on the basis of a pre-selection by each of the MSAs, in line with the peculiarities of each market.

The MSAs chose how to distribute the total number of samples between the two product categories and whether to sample products from both product categories or from only one.

A total of 170[1] samples was collected by the MSAs and 169 were tested by the laboratory: 132 samples of e-liquids and 37 of e-cigarette devices.

The table below provides the number of samples per MSA tested by the laboratory.

Table 2 - **Number of samples tested per MSA**

COUNTRY	MSA	Number of e-cigarette devices	Number of e-liquids	Total products tested
Belgium	Federal Public Service Health, Food Chain Safety & Environment – Federal Environment Inspectorate	/	25	25
	Federal Public Service Economy – Directorate-General for Quality and Safety	9	/	9
Bulgaria	Commission for Consumer Protection	7	18	25
Croatia	State Inspectorate	4	26	30
Finland	National Supervisory Authority for Welfare and Health	3	17	20
Iceland	Housing and Construction Authority	6	31	37
Lithuania	State Consumer Rights Protection Authority	5	15	20
Sweden	Swedish National Electrical Safety Board	3	/	3
	Total	**37**	**132**	**169**

The MSAs chose their preferred sampling channels and collected the products both online and from physical shops. The large majority, 167 (99%) out of the 169 samples, came from physical shops.

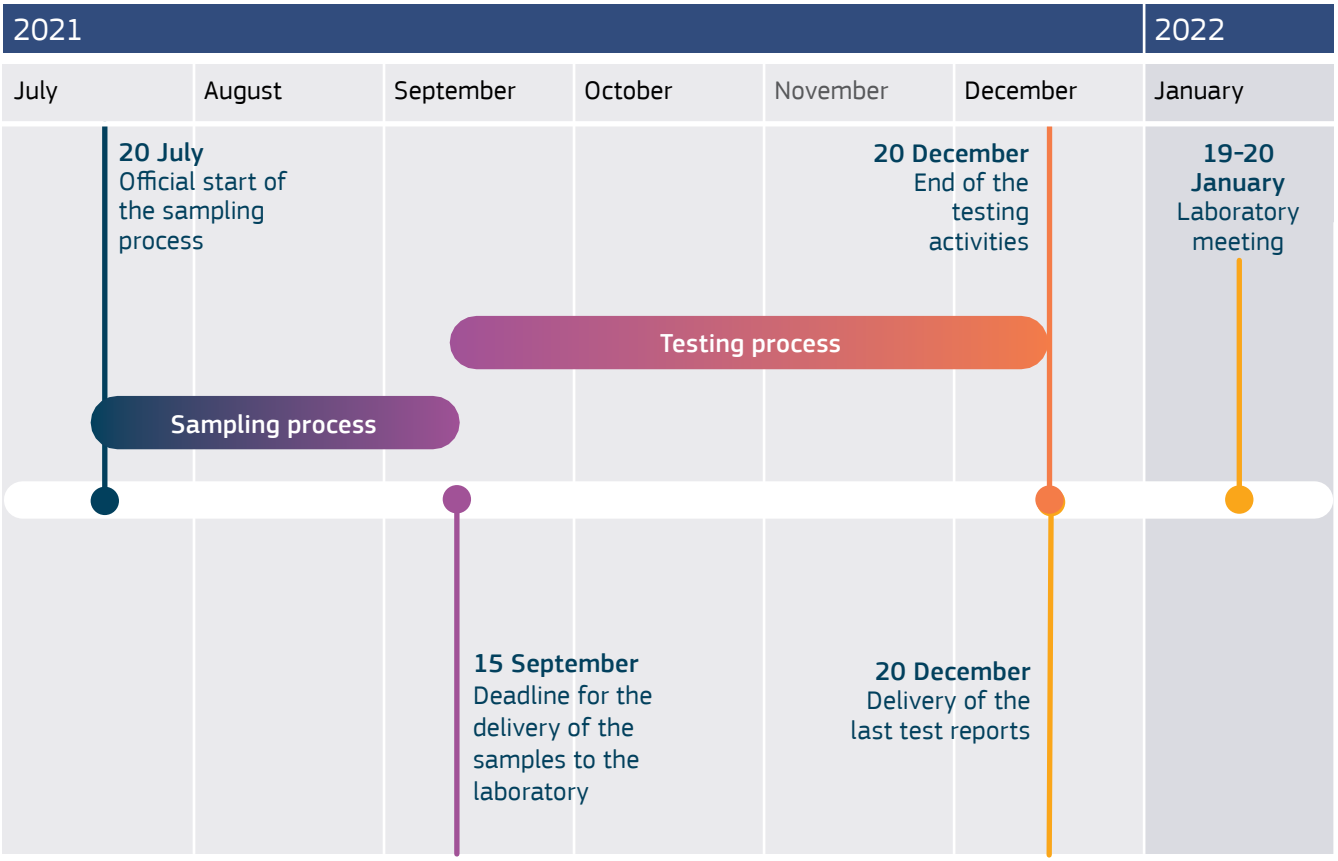
[1] The laboratory was unable to perform most of the tests on one sample of an e-cigarette device because the pods received were not compatible with the battery of the device.

2.2 Testing process

Based on extensive desk research, 207 accredited laboratories located in the EU/EEA were identified. The project team prepared tender specifications and invited the laboratories to submit offers. The MSAs were presented with comparative analyses of the technical suitability and the financial offers of the five laboratories that answered the call. The MSAs selected the laboratory that received the highest points in terms of technical quality; it had the capacity to perform all the requested tests and the pricing was competitive.

The MSAs had 2 months to collect the samples and send them to the laboratory. The testing process encountered no delays and was completed on 20 December. The laboratory meeting took place on 19 and 20 January (in a hybrid format[2]).

Figure 1 - **Timeline of the sampling and testing process**



[2] Members of the Contractor's team and representatives from the Directorate-General for Justice and Consumers of the European Commission (DG JUST) were at the laboratory with the audio-visual team; the MSAs joined the meeting via Zoom.

3. Test results

3.1 Overview of the test results and main findings

A total of 137 out of the 169 samples tested by the laboratory met all the requirements defined in the final testing plan, as shown in the chart below. The remaining 32 samples did not meet at least one of the requirements.

Figure 2
Overall test results (N=169)

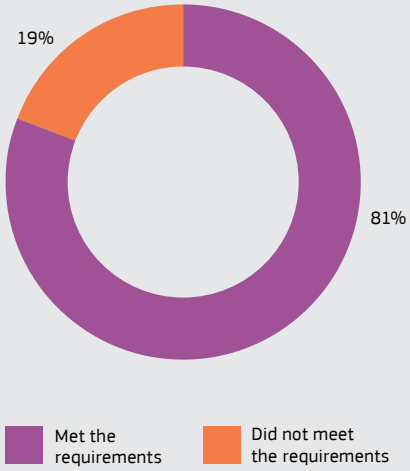
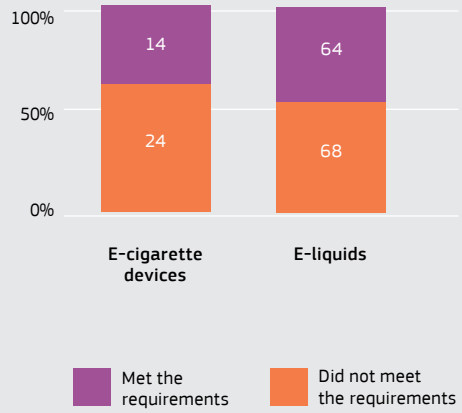


Figure 3
Results of checks on warnings, markings and instructions (N=170)



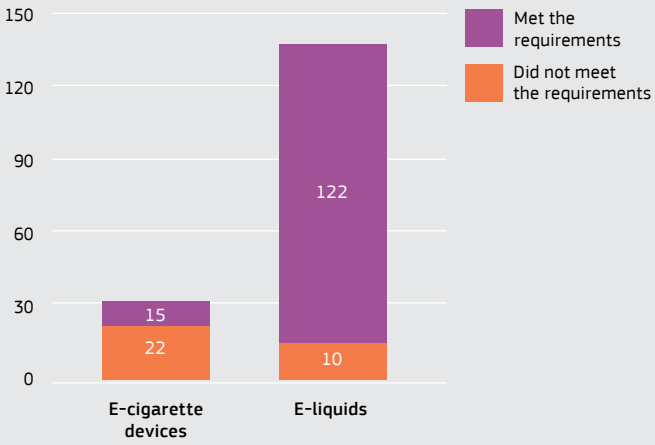
The MSAs performed checks on the warnings, markings and instructions in their national languages: 54% of the samples did not meet the requirements.

The main issues associated with e-cigarette devices were related to: missing addictiveness and toxicity information; missing contact details for the manufacturer/importer; missing warnings in the languages of the country of sale. For e-liquids, the main reasons for products not meeting the requirements were: missing information regarding the amount of nicotine per dose; missing health warnings; missing or incorrect lists of ingredients in descending order of weight.

3.2 Results per product type

The product type with the largest number of samples that did not meet at least one of the requirements was e-cigarette devices. In total, 60% of the e-cigarette devices and 8% of the e-liquids did not meet at least one of the requirements of the testing plan.

Figure 4
Test results for product type (N=169)



The test results per clause are illustrated in the graphs below.

E-cigarette devices

Figure 5 **- Results per clause of CEN/TS 17287:2019 – E-cigarette devices (N=38)**

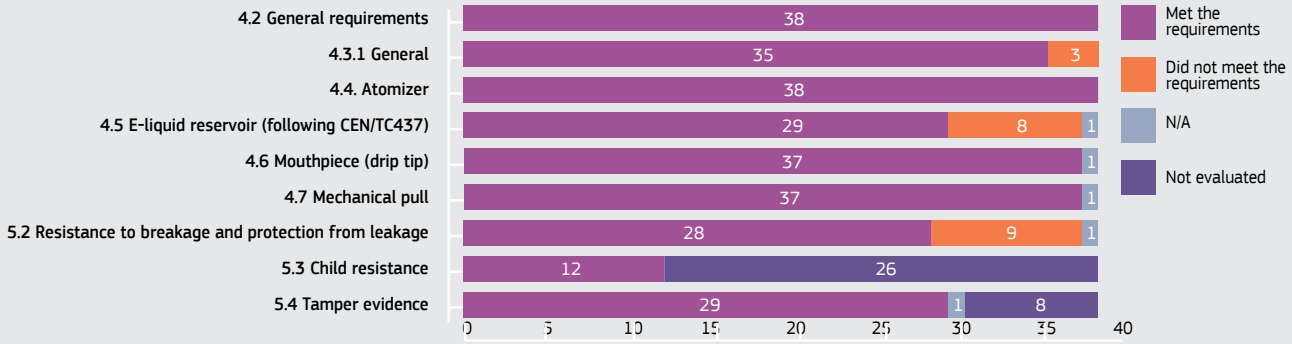
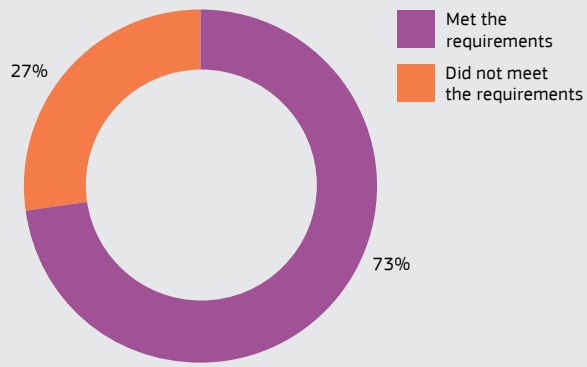


Figure 6
Results per clause 6 of ISO 13127:2012 – Mechanical test methods for re-closable child resistant packaging systems (e-cigarette devices) (N=37)



Emission tests

Emission tests were performed on 10 samples of e-cigarette devices supplied with e-liquids. The laboratory randomly chose one sample from each of the 10 MSAs interested in performing emission tests. The charts below illustrate the results regarding aerosol mass yield, aldehydes emissions, and the emission of heavy metals.

For one sample, the value of aerosol mass yield was 82, more than 16 times the median result. This product is an outlier, and also displayed high values regarding formaldehyde, acetaldehyde and acrolein, as shown below.

Table 3 - **Results of emission testing – Aerosol mass yield**

Overall aerosol mass yield (mg/puff)	
Individual results	4.3
	16
	5
	5.2
	3.1
	5.4
	82
	2.4
	6
	3.5
Average	**13.29**
Maximum	**82**
Minimum	**2.4**
Median	**5.1**

Table 4 - **Results of emission testing – Formaldehyde, acetaldehyde and acrolein**

Formaldehyde (µg/puff)	Formaldehyde (µg/200 puffs)	Acetaldehyde (µg/puff)	Acetaldehyde (µg/200 puffs)	Acrolein (µg/puff)	Acrolein (µg/200 puffs)	Emission of heavy metals (cadmium, chromium, iron, lead, mercury, nickel, titanium, aluminium, copper) (µg/puff)	Emission of heavy metals (µg/200 puffs)
< 0.1	<20	< 0.2	<40	< 0.2	<40	No metals detected	N/A
< 0.1	<20	< 0.2	<40	< 0.2	<40	No metals detected	N/A
0.49	98	0.22	44	< 0.2	<40	Nickel: 0.022 Copper: 0.065 No other metal detected	Nickel: 4.4
0.15	30	< 0.2	<40	< 0.2	<40	No metals detected	N/A
< 0.1	<20	< 0.2	<40	< 0.2	<40	Copper: 0.018 No other metal detected	Copper: 3.6
< 0.1	<20	< 0.2	<40	< 0.2	<40	No metals detected	N/A
8.4	1680	25	5000	1.1	220	Aluminium: 0.41 No other metal detected	Aluminium: 82
0.75	150	< 0.2	<40	< 0.2	<40	No metals detected	N/A
0.49	98	< 0.2	<40	< 0.2	<40	No metals detected	N/A
< 0.1	<20	< 0.2	<40	< 0.2	<40	Lead: 0.013 Aluminium: 0.37 No other metal detected	Lead: 2.6 Aluminium: 60

E-liquids

Figure 7 **- Results per clause – E-liquids**

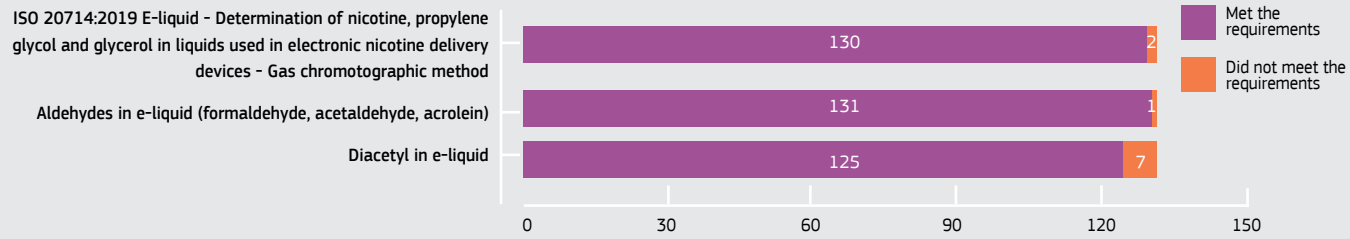


Table 5 - **Density measurement of e-liquids**

Density measurement of e-liquids (g/ml)	
Count values	132
Average	1.14
Maximum	1.26
Minimum	0.99
Median	1.14

3.3 Results per retail channel

Nearly all samples (99%) came from physical shops. Since only two samples were collected online, the test results cannot be considered representative: one out of the two samples collected online did not meet at least one of the requirements of the standards (50%). In total, 19% of the samples collected in physical shops did not meet at least one of the requirements of the standards.

3.4 Conclusions on the test results

The results of the laboratory tests showed that 32 out of the 169 (19%) tested products did not meet at least one of the requirements of the testing plan.

A much higher number of samples of e-cigarette devices did not meet the relevant requirements (22, 60%) compared to e-liquids (10, 8%).

More than half of the products (54%) assessed had incorrect or absent warnings, markings and instructions. Improvements need to be made by the EOs in order to protect EU consumers from e-cigarette devices and e-liquids placed on the Single Market that do not meet the relevant requirements.

E-cigarette devices

The results of the tests on the e-cigarette devices showed that 21 out of the 37 samples tested (60%) did not meet the relevant requirements. The main reasons for this were related to the re-closable child-resistant packaging system of the devices, their resistance to breakage and the systems they use to protect from leakage from the liquid reservoirs. Several products did not meet multiple requirements regarding the containment of the e-liquid.

E-liquids

The results of the tests on the e-liquids showed that 10 out of the 132 tested samples (8%) did not meet the relevant requirements. The majority of samples that did not meet the requirements (7 out of 10) had issues related to the presence of diacetyl, which is a food additive used to provide a buttery flavour. Two samples of e-liquid that did not meet the requirements had issues related to the presence of aldehydes, which are usually considered toxic and could potentially harm the users.

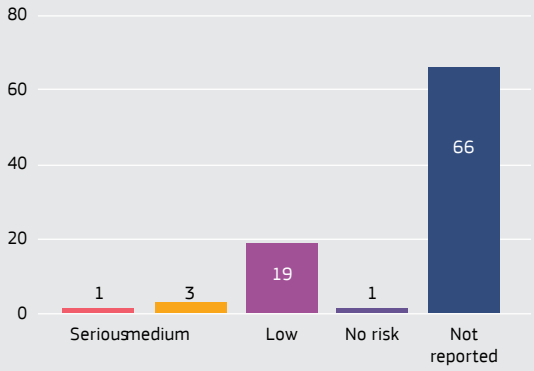
4. Risk assessment and measures

4.1 Risk assessment results

According to the Tobacco Products Directive (2014/40/EU) (TPD), electronic cigarettes and refill containers can only be placed on the market if they comply with the TPD and with all other relevant EU legislation. When assessing whether a product poses a risk, the approach must be based on Decision (EU) 2019/417[3] (the RAPEX Guidelines). To develop the risk assessments, the MSAs used the Risk Assessment Guidelines (RAG) tool[4] managed by the European Commission. Some MSAs could not perform risk assessments because they were not the competent authorities in their jurisdictions.

Figure 8 shows the risk levels (based on the risk assessments performed by the MSAs) of the samples that did not meet the requirements.

Figure 8
Overview of risk level of tested samples (N=90)



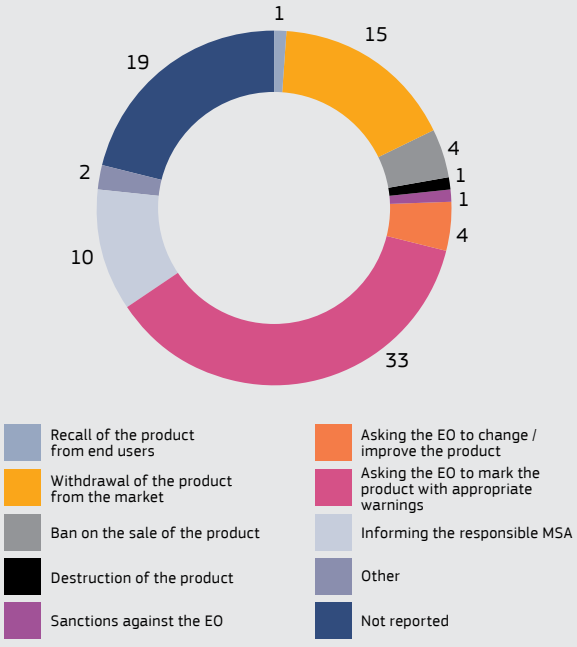
4.2 Corrective measures taken

Based on the test results and the risk assessments performed, the MSAs decide which corrective measure has to be taken regarding the products that do not meet the requirements set out in EU legislation and/or the applicable standards designed to stop dangerous products from appearing on the Single Market. Figure 9 illustrates the main measures taken.

Furthermore, when a serious risk is identified, MSAs are legally obliged to submit a notification in Safety Gate (pursuant to Article 12.1 of the General Product Safety Directive (2001/95/EC) (GPSD)[5]). The RAPEX Guidelines[6] also recommend submitting notifications on measures taken against products posing a less than serious risk.

Following the actions triggered by the joint testing campaign, 12 products were subject to Safety Gate notifications and a notification for one additional product is pending.

Figure 9
Measures taken for products tested within this PSA (N=90)



[3] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32019D0417&from=EN
[4] https://ec.europa.eu/rag/#/screen/home
[5] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32001L0095
[6] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM%3A4390682

5. Conclusions and recommendations

5.1 Conclusions

A total of 19% of the samples tested did not meet at least one of the requirements of the testing plan. A much higher number of samples of e-cigarette devices did not meet the relevant requirements (60%) compared to e-liquids (8%).

More than half of the products assessed had incorrect or absent warnings, markings and instructions. These are an important part of the risk profile of any product as they provide users with crucial information on a product's assembly and correct use, and also provide confidence in relation to compliance with other regulatory controls that address product risk.

Improvements need to be made by the EOs to protect users of e-cigarettes in the EU, as well as others who may come into contact with these products (e.g. young children).

MSAs issued 12 Safety Gate notifications based on the outcome of this PSA (one additional notification is pending). Some MSAs could not perform risk assessments because they were not the competent authorities in their jurisdictions. Generally speaking, MSAs asked the EOs to change/improve the product or banned the sale of the product for samples that were assessed as posing serious or medium risks.

5.2 Recommendations for stakeholders

The recommendations below are based on the outcome of the testing process and discussions among the MSAs during the project.

For consumers

Warnings, markings and instructions. Pay particular attention to the warnings and markings that accompany the products. These should be available in the national languages of the country of sale.

Use of products. Read the instructions supplied with the e-cigarette devices and e-liquids and follow them carefully. Do not change the device settings or the dose of e-liquids provided; it could be unsafe. Always follow the instructions, especially in relation to coil impedance, the type of e-liquid to be used and power settings: this will minimise the risk of dangerous chemicals (aldehydes) being produced while vaping (as a result of the e-liquids or coils overheating). It is important that devices are not used at too high a temperature, as this increases the risk of producing hazardous compounds from either the coil or the e-liquid (as a result of them burning). If the vapour has a burnt taste to it, adjust the settings or replace the coil.

Keep these products out of the reach of children and do not leave them unsupervised While there are built-in controls regarding child accessibility, some products do not meet these requirements and pose an increased risk to children if they come into contact with them..

Recalls and reporting safety problems. Be aware of where information about recalled products can be found and react when you are contacted as part of a recall. Monitor the seller's website and the Safety Gate system (it contains information on recalled or banned products). Any safety issue that is identified should be always reported to the competent MSA.

For EOs

Be aware of your obligations under applicable legislation. Take all necessary precautions to ensure that the products fully comply with the Tobacco Products Directive (2014/40/EU) (TPD), the CLP Regulation and the GPSD.

Perform regular controls on your products.

- It is essential to verify the design against the requirements of the TPD and the GPSD; standards have been developed to assist with this, particularly in relation to child-resistance systems.
- It is also essential to conduct production controls to ensure consistent quality and include specifications that ensure the manufacturing process always follows the verified design. In addition, it is important to establish and maintain a system for collecting information about all of the suspected adverse effects products may have on human health.
- Exercise careful control when developing flavourings to ensure that they do not contain compounds that are considered harmful.
- It is crucial to assess the quality of e-liquids to ensure consistent compositions that meet the requirements of the TPD.
- Determine the content of aerosol emissions across a range of products to ensure that potentially harmful compounds and elements are eliminated.

Recalls. Clearly communicate with consumers on how they should register the products they purchase so they will receive information about recall actions. Make recall notices clear and accessible, and always indicate the hazards posed by the product. Regularly monitor the impact of a recall and adjust the strategy accordingly.

For European and national authorities

Keep e-cigarette devices and e-liquids under surveillance. Considering that one out of five tested samples did not meet the requirements of the testing plan and more than half of the samples did not meet the requirements on warnings, markings and instructions, these products should be kept under surveillance (perform additional tests and formal checks). These breaches in compliance, although sometimes only seen as a technicality by some manufacturers, have a direct effect on consumer risk. They also indicate that there is an increased risk of other poor practices in relation to non-technical requirements that increase the likelihood of physical or chemical hazards, and therefore the risks presented by the products.

Increase cooperation between authorities who receive notifications and MSAs. Product notifications are a clear indicator of risk, but also provide a valuable database against which MSAs can conduct targeted interventions aimed at securing compliance and reducing risk.

Engage with standardisation organisations. With the aim of improving the safety of these products, the development of European standards for e-cigarettes and liquids is suited in particular to establish clearer test methods against which the risks of those products can be assessed.

1. What is CASP?

The Coordinated Activities on the Safety of Products (CASP) enable Market Surveillance Authorities (MSAs) from EU/EEA countries to cooperate and to reinforce the safety of products placed on the Single Market.

Product-specific activities (PSAs) test different types of products that may pose a risk to consumers. The products are selected and collected by the MSAs involved and are examined using a commonly agreed testing plan.

Horizontal activities (HAs) provide a forum for MSAs to exchange ideas and best practices. Under the guidance of a technical expert, they develop common approaches, procedures and practical tools for market surveillance.

Hybrid activities facilitate horizontal discussions and conduct testing campaigns. The results are used to develop common approaches and methodologies.

CASP 2021 includes five PSAs, three HAs and one hybrid activity. They were pre-selected by the participating MSAs through a consultation organised by DG JUST.

Product-specific activities (PSAs)

- Toys from non-EU webshops
- Electric toys
- Reclined cradles and baby swings
- E-cigarettes and liquids
- Personal protective equipment

Hybrid activity

- Dangerous counterfeit products

Horizontal activities (HAs)

- Online market surveillance
- Risk assessment and management
- Crisis preparedness and management

Roles and responsibilities

EISMEA
- The contracting authority – manages the administrative relationship with the contractor on behalf of DG JUST
- Monitors and approves all contractual deliverables

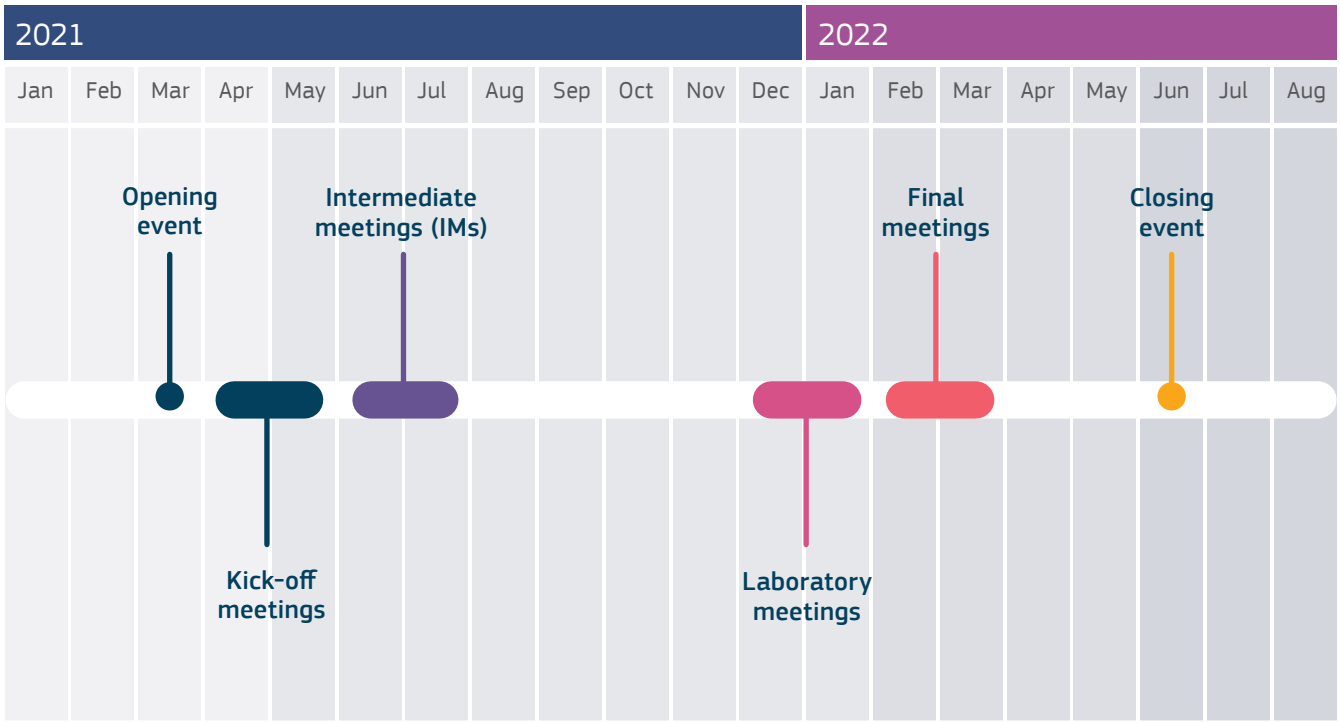
Contractor EY/Pracsis
- Coordinates the implementation and organisation of the activities
- Provides technical & logistical background
- Responsible for reporting, communication and the dissemination of the outcomes

Market Surveillance Authorities of EU/EEA Member States

DG JUST
- Oversees the planning and execution of the CASP projects
- Ensures operational leadership, management and successful implementation
- Supports the participating MSAs by providing guidance

Technical expert (one per PSA)
- Provides technical advice and guidance to MSAs
- Helps with drafting the sampling and testing plan and selecting the most suitable laboratory
- Analyses results, helps with assessing the identified risks and proposes recommendations

2. PSA work plan



Continuous internal communication via the Wiki Confluence platform

INCEPTION	SAMPLING AND TESTING	REPORTING	EXTERNAL COMMS
Desk research	Laboratory tendering process	Risk assessment	Development of a comms toolkit
Scoping interviews	Laboratory selection and contracting	Coordination of measures adopted by MSAs	Development of communication messages
Draft testing and sampling plan	Sampling and transportation	Drafting of final reports	Launch of communications campaign
Laboratory mapping	Testing process and test reports	Disposal or return of samples to MSAs	Assessing the impact

3. PSA Tools & processes

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Pre-CASP process
DG JUST conducts a priority-setting exercise to select the product categories. The five CASP 2021 product categories were selected by the participating MSAs through a consultation organised by DG JUST.

1

Validation of the testing and sampling plans
The technical experts draft the plans based on MSA feedback and the available budget. The drafts are presented at the KoMs, then finetuned and validated by the MSAs via the Wiki.

2

Laboratory selection
The contractor's team maps the laboratories and contacts them to collect prices and other information. The tendering process is launched after the KoM, and the offers are evaluated. During the intermediate meetings, the participating MSAs decide which laboratory to select.

3

Collection and transportation of samples
The MSAs collect the relevant samples from their national markets and register them in a codification file. After performing preliminary checks, the MSAs send the samples to the laboratory.

4

Testing and delivery of test reports
The laboratory tests the samples according to the agreed testing plan and uploads the test reports to the Wiki. The MSAs ask for clarification if necessary, and approve the reports.

5

Risk assessment
The technical expert and the MSAs develop scenarios based on selected samples during the laboratory meeting and analyse the risks. MSAs perform risk assessments on all samples that do not meet legal requirements.

6

Upload scenarios to the RAG tool
The scenarios developed during the project are uploaded to the RAG tool.

7

Measures adopted by the MSAs
The MSAs take appropriate measures on the products in question and report them on Safety Gate.

8

External communications
The external communication activities are launched at the closing event. This marks the start of a 2–3-week pan-European communications campaign.

Tools

Audio-visual clips addressed to consumers and a general audience are produced for each PSA, the hybrid activity, and the overall CASP 2021 project.

Infographics addressed to economic operators are developed for the CASP 2021 project, for each PSA and for the hybrid activity.

Final reports are produced for each activity and for the CASP 2021 project. They are translated into all official EU languages plus Norwegian and Icelandic.

Channels

The communication material is disseminated using:

- *The Safety Gate website*
- *The EC CASP website*
- *DG JUST social media*
- MSAs' national communication channels
- Relevant press and other stakeholders

EUROPEAN COMMISSION
Directorate-General for Justice and Consumers
Directorate Consumers
Unit E.4 Product Safety and Rapid Alert System
Email: *JUST-RAPEX@ec.europa.eu*

Publications Office of the European Union

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