EN

European Commission

CASP2022

Coordinated Activities on the Safety of Products

Ozone air purifiers and sterilisers

Final Report

Justice and Consumers

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List of abbreviations

ABBREVIATION	DESCRIPTION
CASP	Coordinated Activities on the Safety of Products
DG JUST	Directorate-General for Justice and Consumers of the European Commission
EC	European Commission
EEA	European Economic Area
EN	European Standard
EU	European Union
LVD	Low Voltage Directive (2014/35/EU)
MSA	Market Surveillance Authority
PSA	Product-specific activity
RAPEX	The Rapid Exchange of Information System
The RAPEX Guidelines	Decision (EU) 2019/417
UV	Ultraviolet

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 jointly ensure that unsafe products are swiftly removed from the Single Market. This activity focused on ozone air purifiers and sterilisers. The products were sampled and tested following commonly agreed criteria in a European laboratory selected by participating MSAs.

Product scope

Mains operated and floor or surface standing ozone air purifiers and sterilisers.

Main testing criteria

The testing plan included:

- a selection of clauses from the European Standard (EN) 60335-1:2012 Safety of household and similar electrical appliances (used in conjunction with EN 60335-2-65 on air cleaning appliances);
- EN 60335-2-109 – Clause 32 Radiation, toxicity and similar hazards;
- EN 62471:2008 Photobiological safety of lamps and lamp systems.

Results

- In total, 14 out of the 16 tested samples did not meet at least one of the requirements covered by the testing plan.
- The clauses of EN 60335-1:2012 that produced a particularly large number of samples that did not meet the requirements were Clause 7 – Marking (11 samples), Clause 8 – Protection of live parts (7 samples), Clause 22 – Construction (9 samples) and Clause 29 – Clearances, creepage distance and solid insulation (8 samples).
- In total, 7 out of 16 samples did not meet the requirements of EN 62471:2008 Photobiological safety of lamps and lamp systems.
- In total, 10 out of 16 samples did not meet the requirements of Clause 32 of EN 60335-2-109:2010 – Radiation, toxicity and similar hazards.

Conclusions

The activity showed alarming results, as 14 out of 16 samples did not meet at least one of the requirements of the testing plan. This indicates that economic operators are facing difficulties in terms of complying with the relevant standards; not only with those related to product-specific hazards but also with the general electrical safety requirements.

Following the actions triggered by the joint testing campaign (up to 14 April 2023), two products were withdrawn from the market. The measures for the other products that did not meet the requirements are still pending.

Key recommendations

For consumers

- Use the products in an appropriate way and carefully **follow the instructions on time and modality of use and pay attention the warnings** placed on the devices. Only use spare parts approved by the manufacturer.
- Be careful when using ozone production devices. **Ozone** is **highly corrosive** and poorly designed devices producing high levels of this substance can impair electrical safety.

For economic operators

When you design such products, ensure that:

- ultraviolet (UV) radiation does not come into direct contact with the eyes or skin;
- the product's filter cannot be removed without the use of a tool and the product cannot be operated without a filter;
- the product does not produce ozone levels that are hazardous for the user.

Follow the basic principles of **design for electrical product safety.**

For public authorities

- Keep focusing market surveillance efforts on ozone air purifiers and sterilisers. This is an **emerging product sector** that requires significant intervention to ensure conformity and to manage the current risks.
- **Educate consumers** about the risks these products present.

For standardisation organisations

Consider developing a standard specifically for this class of products, given their apparent popularity and the difficulties that manufacturers appear to be having in terms of making a safe and compliant product.

1. Overview of the activity

1.1. Participating MSAs

In total four MSAs from four EU Member States participated in the Ozone air purifiers and sterilisers product-specific activity (PSA).

Table 1 - **List of participating MSAs**

COUNTRY	MSA
Czechia	Czech Trade Inspection Authority
Slovak Republic	Slovak Trade Inspection
Slovenia	Market Inspectorate of Republic of Slovenia
Sweden	Swedish National Electrical Safety Board

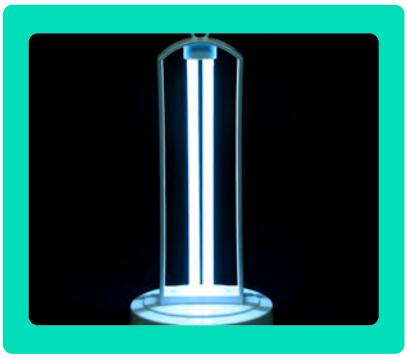
1.2. Product scope and testing criteria

1.2.1. Product scope

The MSAs agreed to restrict the product scope to mains operated and floor or surface standing devices.

Battery operated products and commercial or built-in products were out of the scope of this activity.

OZONE AIR PURIFIER



UV LAMP

1.2.2. Testing criteria

Ozone air purifiers and sterilisers are not regulated by product-specific legislation, other than the Low Voltage Directive (2014/35/EU) (LVD). EN 60335-2-65 can be used to assess the electrical safety of air cleaning appliances for household and similar purposes, but there are no specific requirements available to assess the ozone emissions and safety of UV radiation sources for these specific products. Therefore, the most appropriate harmonised standards were used by analogy[1].

Based on discussions with the MSAs and the technical expert, it was therefore agreed that the testing plan would include the requirements of the following standards:

- **EN 60335-1:2012 Safety of household and similar electrical appliances.** This standard provides the main requirements for all mains operated domestic appliances, and is used in conjunction with relevant specialist standards, such as EN 60335-2-65 Particular requirements for air cleaning appliances. A selection of tests using the relevant clauses was performed in order to identify the main electrical and mechanical risks posed by the samples.
- **EN 60335 Household and similar electrical appliances – Part 2-109: Particular requirements for UV radiation water treatment appliances.** In particular, Clause 32 Radiation, toxicity and similar hazards was used to assess whether the ozone generated exceeded the limit values set out in the standard.
- **EN 62471:2008 Photobiological safety of lamps and lamp systems.** This standard was used by the laboratory as a benchmark for the safety of the UV radiation source and, although individual clauses were not addressed, an opinion was offered as to whether the lamp system in question complied.

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

[1] The following standards were used as directly applicable standards to this class of product: EN 60335-1:2012 Generic standard for mains operated household appliances; EN 62471:2008 Photobiological safety of lamps and lamp systems.

2. Sampling and testing

2.1. Sampling distribution and sampling channels

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. A total of 18 samples was collected by the MSAs both online (15 samples) and from physical shops (three samples). One sample was eventually considered out of scope, as it is intended for professional use only and it is not available on the market for consumers[2]. Moreover, one sample was purchased online by the Swedish MSA but never arrived at the MSA's premises and, therefore, it was not tested.

Table 2 - **Number of samples collected by participating MSAs**

COUNTRY	MSA	NUMBER OF SAMPLES
Czechia	Czech Trade Inspection Authority	4
Slovak Republic	Slovak Trade Inspection	4
Slovenia	Market Inspectorate of Republic of Slovenia	4
Sweden	Swedish National Electrical Safety Board	6
	TOTAL	18

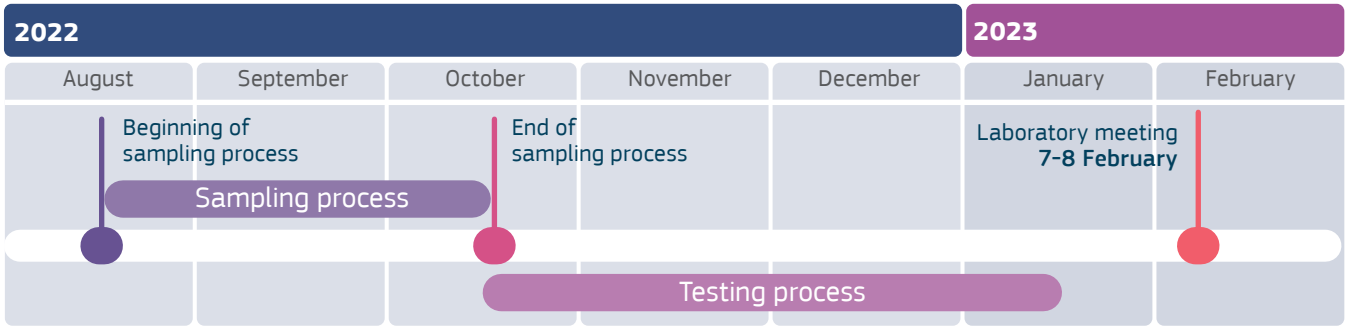
2.2. Testing process

The testing laboratory for this activity was selected through a tender procedure launched in May 2022. The tender specifications were sent to 209 laboratories in the EU/EEA that had been identified following the project team's laboratory engagement strategy. Each laboratory was asked to submit an offer including the elements mentioned in the tendering document, such as detailed information on pricing and supporting documents supplying evidence of certification, the relevant experience of experts and test reports. Four laboratories submitted an offer within the given timeframe and all of them were invited to an interview to further discuss their offer.

During the intermediate meeting the MSAs were presented with comparative analyses of the technical quality and financial aspects of the offers received from the laboratories. The MSAs selected the laboratory that was awarded the highest number of points in terms of the technical quality.

Following the selection of the laboratory, the MSAs were given three months to collect samples and send them to the laboratory. The testing process encountered no delays and was completed on 24 January 2023. The laboratory meeting took place on 7–8 February 2023.

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



[2] The product was considered out of scope and the results of the testing are not included in the figures of this report.

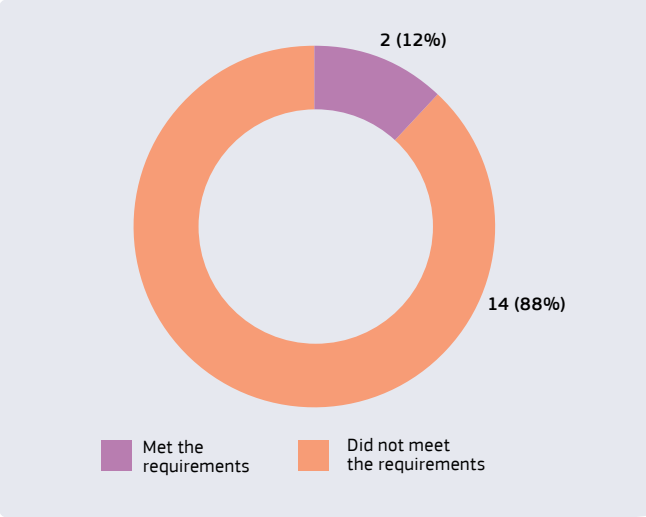
3. Test results

3.1. Overview of the test results and main findings

A total of 14 out of 16 tested samples did not meet at least one of the requirements outlined in the testing plan, as shown in *Figure 2*.

The MSAs performed checks on warnings, markings and instructions in their national language(s). Out of 16 samples, 10 did not meet the requirements. The most common non-compliance issues were: missing warnings and markings; product information not in the official language; incomplete instructions for appliances containing UV-C emitters.

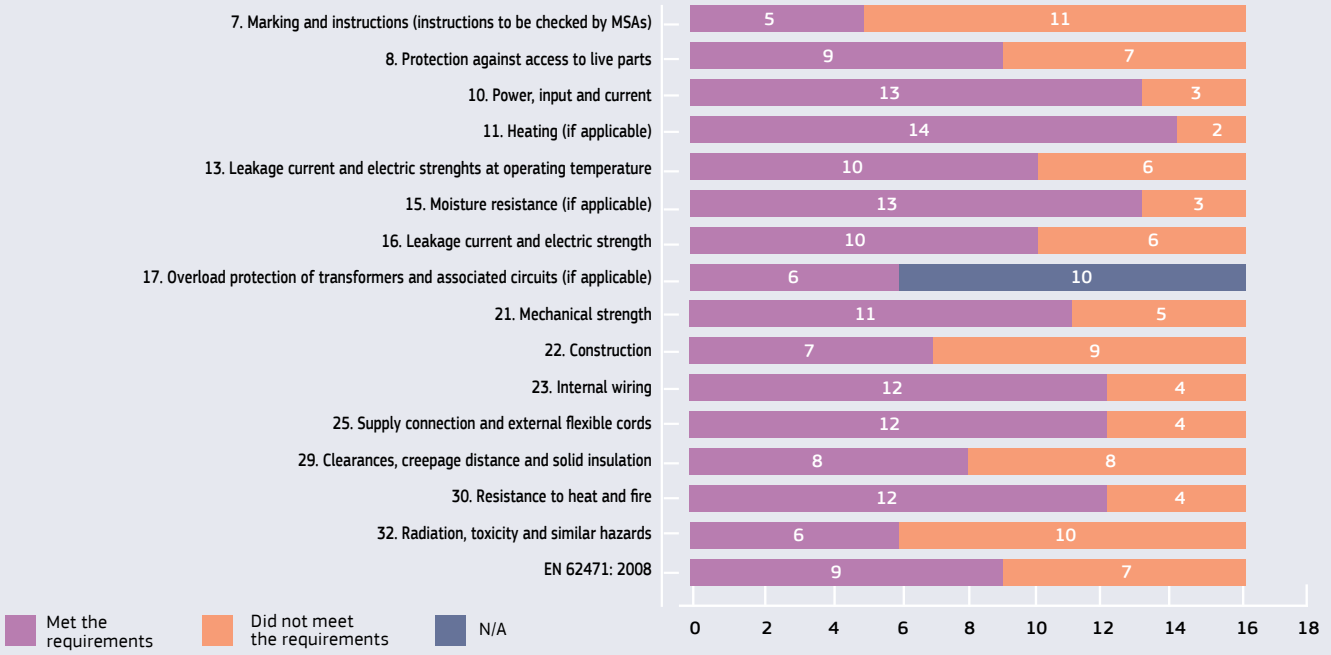
Figure 2 - **Overall test results (excluding warnings, markings and instructions) (N=16)**



3.2. Results per clause

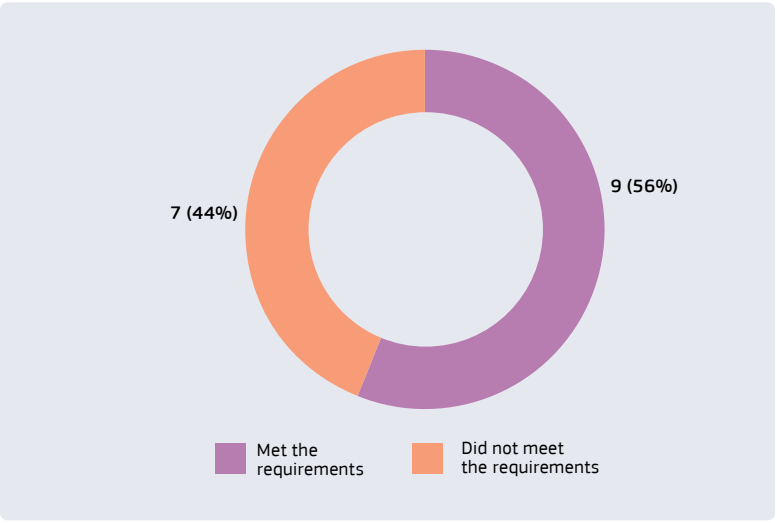
Looking at the results per clause of EN 60335-1:2012, clauses that produced a particularly large number of samples that did not meet the requirements included Clause 7 (Marking), Clause 8 (Protection against access of live parts), Clause 22 (Construction) and Clause 29 (Clearances, creepage distance and solid insulation). *Figure 3* provides a more detailed overview of the test results per clause.

Figure 3 - **Test results per clause – EN 60335-1:2012 (N=16)**



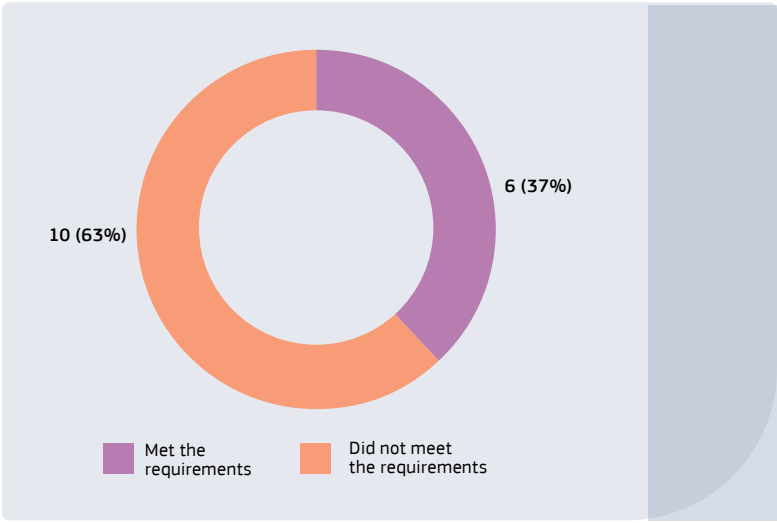
When tested against EN 62471:2008 Photobiological safety of lamps and lamp systems, seven out of 16 samples did not meet the requirements (*see Figure 4*).

Figure 4 - **Results – EN 62471:2008 (N=16)**



When tested against EN 60335-2-109:2010, Clause 32 Radiation, toxicity and similar hazards, 11 out of 16 samples did not meet the requirements (*see Figure 5*).

Figure 5 - **Results, EN 60335-2-109:2010 – Clause 32 Radiation, toxicity and similar hazards (N=16)**



3.3. Conclusions on the test results

14 out of 16 samples did not meet the requirements outlined in the testing plan taking into consideration the tests performed by the laboratory and the checks of the MSAs on warnings, markings and instructions. Some samples did not meet certain technical requirements related to the specific function and purpose of the product, for which there are no directly applicable harmonised standards and for which other standards were applied by analogy. However, there was a considerable number of samples that did not meet the electrical safety requirements, for which the risk profile is well established in relation to all electrical products.

Ozone air purifiers and sterilisers are a relatively new product type, and the test results indicate that manufacturers are facing challenges in complying with the relevant health and safety requirements and standards. This may be because of the immaturity of the market or the lack of directly relevant product standards, although even basic electrical safety requirements, which are founded on well-established engineering principles, were at times not respected.

Some of the main findings that emerged from the activity are the following:

- The tested products present hazards that may pose significant risk to users, either relating to the principles of basic electrical safety, or to the specific function of the product.
- Designers and manufacturers have difficulties in terms of mitigating specific hazards of new products, particularly when there are no standards available to quantify them. It appears that many players on the emerging market of air purifiers have not adequately addressed the safety requirements of the LVD[3] that should always be met.
- There is no specific requirement to adequately evaluate the efficacy of these products, which means that a product may be safe in terms of its emissions, but may actually not fulfil its intended purpose (cleaning the air).

Main risks

The main types of risks identified in the tests are the following:

- **Electric shock** and **fire**, for the samples that did not meet the electrical requirements.
- **Exposure to UV radiation.** This can cause serious injury to eyes and skin when the exposure is lengthy enough.
- **Exposure to ozone.** This naturally occurring gas is an oxidiser and, when it occurs in concentrations above the specified limits, can be harmful to the respiratory system for any consumer, but particularly for those with specific vulnerabilities (e.g. persons suffering from asthma).
- **Foreseeable misuse.** There are inherent risks presented by these products. Hazards may not always be obvious to the user, and nor are safe modes of use. Therefore, **instructions and warnings** are crucial to managing risks.

  For example, if the instructions do not clearly state that the user shall leave the room while the ozone air purifier is turned on, the user might stay in the room and be exposed to ozone levels above limit values. Furthermore, products may have parts that are replaceable during the expected lifetime of the product. If these are not exactly the same design and specification as the original part, they may impact on the risk presented by the product as it may no longer be the same product as was originally designed and manufactured.

[3] EUR-Lex - 32014L0035 - EN - EUR-Lex (europa.eu)

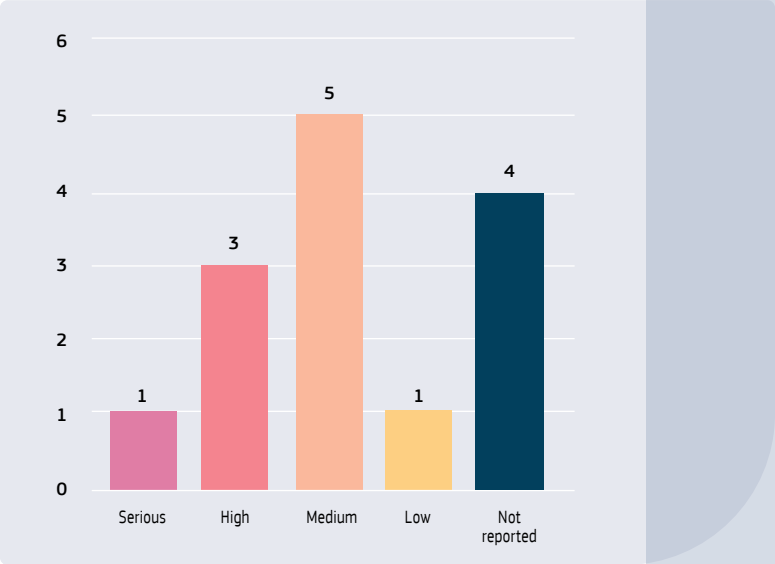
4. Risk assessments and measures

4.1. Risk assessments results

All devices directly connected to the mains need to comply with the LVD. When assessing whether a product poses a risk, the principles laid down in the RAPEX Guidelines[4] should be respected. These guidelines set out a risk assessment method that can be used by MSAs to assess the level of risk posed by consumer products to the health and safety of consumers, and to decide whether a Safety Gate notification is necessary. A specific Risk Assessment Guidelines[5] tool, or 'RAG tool', for performing risk assessments (which takes into account the principles provided in the RAPEX Guidelines), is available on the RAPEX website and in the RAPEX application.

Figure 6 shows the risk levels (based on the risk assessments performed by the MSAs) of the samples that did not meet the requirements.

Figure 6 - **Overview of risk levels of the samples that did not meet the requirements (N=14)**



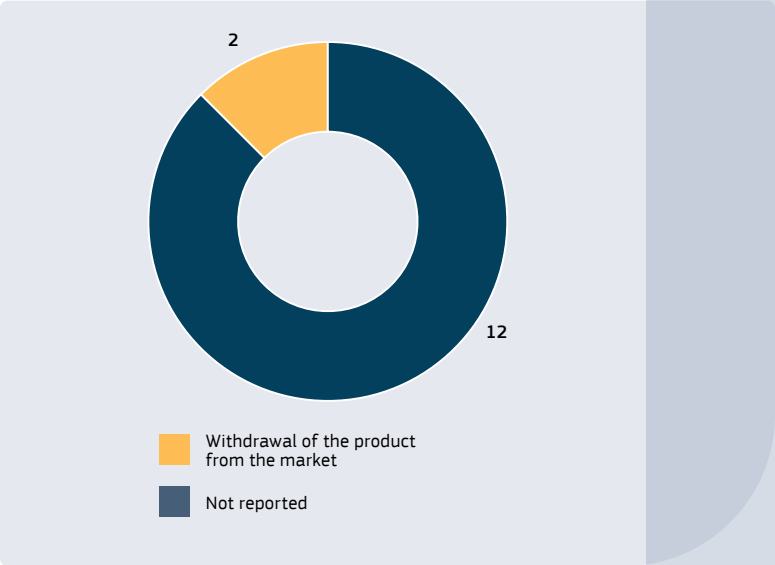
4.2. Corrective measures

Based on the test results and the risk assessments performed, the MSAs decide which corrective measures have to be taken regarding the products that do not comply with EU legislation and/or the applicable standards, which are developed to assist with designing safe and compliant products. *Figure 7* displays the corrective measures taken in relation to the products that did not meet the requirements.

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)[6]. The RAPEX Guidelines[7] also recommend submitting notifications on measures taken against products posing a less than serious risk.

Following the actions triggered by the joint testing campaign (up to 14 April 2023), two products were withdrawn from the market. The measures for the other products that did not meet the requirements are still pending.

Figure 7 - **Measures adopted for samples that did not meet the requirements (N=14)**



[4] Commission Implementing Decision (EU) 2019/417 of 8 November... - EUR-Lex (europa.eu)
[5] RAG ECL V10 (europa.eu)
[6] The Regulation (EU) 2023/988 on general product safety has been published in the Official Journal on 23 May 2023: EUR-Lex - 32023R0988 - EN - EUR-Lex (europa.eu). It enters into force on 12 June 2023 and into application on 13 December 2024.
[7] EUR-Lex – 4390682 – EN – EUR-Lex (europa.eu)

5. Conclusions and recommendations

5.1. Conclusions

Ozone air purifiers and sterilisers are a relatively new product type, and they are not regulated by product-specific legislation other than LVD. While there is a standard (EN 60335-2-65) that can be used to assess the electrical safety of air cleaning appliances for household and similar purposes, there are no specific requirements available to assess the ozone emissions or the safety of UV radiation sources for these specific products. Therefore, the most appropriate available harmonised standards were used by analogy.

The activity showed alarming results, as 14 out of 16 samples did not meet the requirements outlined in the testing plan. This element indicates that economic operators face difficulties in terms of mitigating specific hazards of new products, as there are no standards to quantify these and they can only use standards by analogy.

The main identified risks are: electric shock; fire; exposure to UV radiation above the limits, which may cause injury to eyes and skin; exposure to ozone levels above the limits, which may harm the respiratory system; risks related to the misuse of products due to incomplete, incorrect or missing warnings, markings and instructions.

Following the actions triggered by the joint testing campaign (up to 14 April 2023), two products were withdrawn from the market. The measures for the other products that did not meet the requirements are still pending.

5.2. Recommendations for stakeholders

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

For consumers

Exercise caution when purchasing ozone air purifiers and sterilisers, as there are **general electrical risks** as well as **product-specific risks** present in all products sampled and tested.

Use the products in an appropriate way and carefully **follow the instructions** on time and modality of use and **pay attention to the warnings** placed on the devices. Only use spare parts approved by the manufacturer.

This is a new type of product and problems could occur across the entire market (ranging from reputable brands to no-name producers).

Be careful when using ozone production devices. Ozone is highly corrosive and poorly designed devices producing high levels of this substance can impair electrical safety.

For economic operators

When you design such products, ensure that, among other things, the following requirements are met:

- UV radiation does not come into direct contact with the eyes or the skin;
- the product's filter cannot be removed without the use of a tool and the product cannot be operated without a filter;
- the product does not produce ozone levels that are hazardous for the user.

Although there is **no unique product-specific standard** that can be applied at the design stage, the **basic principles of design for electrical product safety** are well established and must be followed.

There are appropriate standards that can be used to assess the design relating to the product-specific features, and these should be used to ensure that products are 'safe' according to the LVD and do not present a risk of injury to users and others.

Communicate about the **performance of the product** and provide **information on how and where to use it.**

For public authorities

Keep focusing market surveillance efforts on ozone air purifiers and sterilisers. This is an emerging product sector that requires significant intervention to ensure conformity and to manage the current risk. Educate consumers about the risks these products present.

For standardisation authorities

Consider **developing a standard specifically for this class of products**, given their apparent popularity and the difficulties that manufacturers appear to be having in terms of making a safe and compliant product.

Consider developing **requirements to adequately evaluate the efficacy** of these products.

1. What is CASP?

The Coordinated Activities on the Safety of Products (CASP) enable market surveillance authorities from European Union / European Economic Area countries to cooperate and to reinforce the safety of products placed on the Single Market.

CASP 2022 includes six product-specific activities and four horizontal activities

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

Toys with magnets | **Chemicals in toys** | **Baby strollers** | **Ozone air purifiers and sterilisers** | **Travel adaptors** | **Hygiene products**

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

Communication booster | **Risk assessment and management** | **Online market surveillance** | **Goods and products sold at street markets**

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

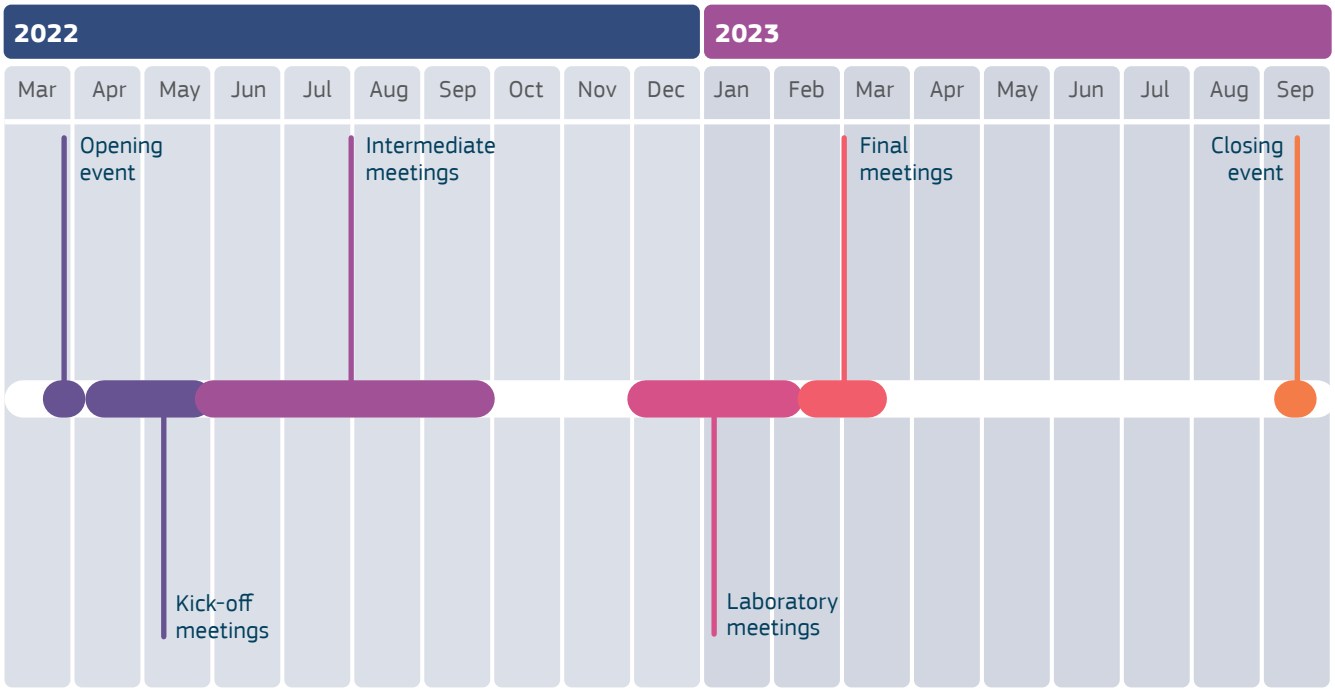
Contractor EY/Pracsis
- Coordinates the implementation and organisation of the activities
- Provides technical & logistical background
- Responsible for reporting, communication and the dissemination of the outcomes

Market Surveillance Authorities of European Union / European Economic Area Member States

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

Technical expert (one per product-specific activity)
- Provides technical advice and guidance to market surveillance authorities
- 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. Product-specific activities 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 market surveillance authorities	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 market surveillance authorities	Assessing the impact

3. Product-specific activities tools & processes

0

Pre-CASP process
DG JUST conducts a priority-setting exercise to select the product categories.
The six CASP 2022 product categories were selected by the participating market surveillance authorities through a consultation organised by DG JUST.

1

Validation of the testing and sampling plans
The technical experts draft the plans based on market surveillance authority feedback and the available budget. The drafts are presented at the kick off meeting, then finetuned and validated by the market surveillance authorities 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 kick off meeting, and the offers are evaluated.
During the intermediate meetings, the participating market surveillance authorities decide which laboratory to select.

3

Collection and transportation of samples
The market surveillance authorities collect the relevant samples from their national markets and register them in a codification file. After performing preliminary checks, the market surveillance authorities 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 market surveillance authorities ask for clarification if necessary, and approve the reports.

5

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

6

Upload scenarios to the Risk Assessment Guidelines tool
The scenarios developed during the project are uploaded to the Risk Assessment Guidelines tool.

7

Measures adopted by the market surveillance authorities
The market surveillance authorities 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 will be followed by a 2–3-week pan-European communications campaign.

Tools

Audio-visual clips addressed to consumers and a general audience are produced for each product-specific activity and the overall CASP 2022 project.
Infographics addressed to economic operators are developed for the CASP 2022 project, for each product-specific activity.
Final reports are produced for each activity and for the CASP 2022 project. They are translated into all official EU languages plus Norwegian and Icelandic.

Channels

The communication material is disseminated using:

- The EC CASP website
- Market surveillance authorities 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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