



Market Surveillance

Cosmetics: Sunscreens

Final Report

JACOP 2025

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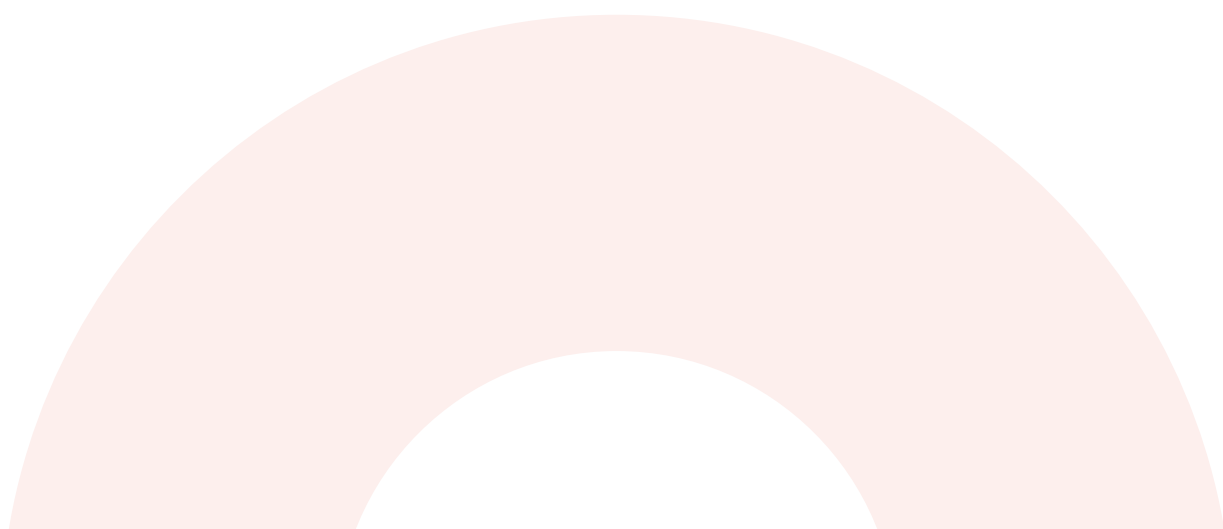
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LIST OF ABBREVIATIONS

EEA	European Economic Area
EN	European Standard
EU	European Union
HDRS	Hybrid Diffuse Reflectance Spectroscopy
ISO	International Organisation for Standardisation
JACOP	Joint Action on the Compliance of Products
MSA	Market Surveillance Authority
PSA	Product-Specific Activity
SPF	Sun Protection Factor
UVA	Ultraviolet A radiation
UVB	Ultraviolet B radiation

Part 1

TEST RESULTS AND RECOMMENDATIONS

EXECUTIVE SUMMARY

OBJECTIVES OF THE ACTIVITY

Product-Specific Activity (PSA) 4 focused on assessing the compliance of sunscreen products available on the EU/EEA market claiming a Sun Protection Factor (SPF) and UVA protection. The sample set comprised sunscreen products intended to protect the skin from UV radiation, with a particular focus on high (SPF 30-50) and very high (SPF 50+) protection categories.

Each sample was tested for three official standards:

- EN ISO 24443:2021 for UVA protection,
- EN ISO 24444:2020 for SPF (UVB) determination using *in vivo* testing,

- EN ISO 23675:2024 for SPF (UVB) determination using *in vitro* testing.

One of the objectives of PSA 4 was to enable a direct comparison between the well-established *in vivo* SPF method and the recently published *in vitro* method, to assess their correlation and support the use of reliable, non-human testing approaches.

RESULTS AND CONCLUSIONS

Testing identified non conforming results related to SPF performance.¹ These results were based on *in vivo* and/or *in vitro* testing showing SPF values below the labelled SPF. Non conformities were also identified with the EU requirement for UVA protection (minimum one third of the labelled SPF), as well as marking and warning deficiencies.

Within the scope of PSA 4, of 74 products tested, 33 (45%), were assessed by MSAs as non conforming with respect to UV protection performance (SPF and/or UVA). These results should be interpreted in the context of a sampling approach combining targeted,

risk-based selection with non-targeted sampling, and **are therefore not representative of the overall sunscreen market.**

The risk assessment confirmed that misleading SPF or UVA claims may pose a health risk, as consumers may be exposed to higher levels of UV radiation than expected. Follow-up measures taken by MSAs included product withdrawals, sales bans, destruction, recalls, and other corrective actions proportionate to the risk identified.

A strong correlation between *in vivo* and *in vitro* SPF testing methods was observed.

¹ Assessment of the SPF and UVA protection aspects in this activity is based on Commission Recommendation 2006/647/EC, which is not legally binding. Consequently, any deviations identified between the test results and the criteria set out in this Recommendation are referred to in this report as "non-conformities". By contrast, "non-compliance" refers to cases where the assessed cosmetic product was found to be in breach of legally binding requirements, namely Regulation (EC) No 1223/2009 on cosmetic products or Regulation (EU) No 655/2013 on cosmetic claims.

OVERVIEW OF THE ACTIVITY

PARTICIPATING MSAs

A total of 11 MSAs participated in the activity, including both full and testing only participants.

Table 2 provides an overview of the participating MSAs..

PRODUCT SCOPE

The activity covered testing of sunscreen products intended to protect the skin from UV radiation, in line with the EU Cosmetics Regulation 1223/2009,² Cosmetic Claims Regulation 655/2013,³ and Commission Recommendation 2006/647/EC on sunscreen efficacy and claims,⁴ which defines the protection categories (**Table 1**).⁵

The scope included:

- **Primary:** Sunscreen products intended for sun exposure claiming high or very high protection (SPF 30-50 and SPF 50+);
- **Secondary:** Day creams (moisturisers) claiming a sun protection factor (SPF 30, 50 or 50+).

Table 1: Protection categories (Commission Recommendation 2006/647/EC)

Labelled category	Labelled sun protection factor	Measured sun protection factor
Low protection	6	6–9.9
	10	10–14.9
Medium protection	15	15–19.9
	20	20–24.9
	25	25–29.9
High protection	30	30–49.9
	50	50–59.9
Very high protection	50+	≥ 60

TESTING CRITERIA

UV radiation from the sun comprises (shorter) UVB radiation and (longer) UVA radiation; UVB is primarily responsible for sunburn and is the main contributor to skin cancer risk, while UVA also contributes to skin cancer risk and erythema (reddening of the skin), and causes premature skin ageing.

Products were assessed for UVA protection using the *in vitro* standard EN ISO 24443:2021, and for SPF using two validated methods: EN ISO 24444:2020 (*in vivo*) and EN ISO 23675:2024 (*in vitro*). A key objective of PSA 4 was to enable a comparison between the *in vivo* and *in vitro* SPF methods. While the activity focused on this comparison, it is acknowledged that the EU framework

² Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

³ Commission Regulation (EU) No 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products.

⁴ Commission Recommendation of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto (2006/647/EC)

⁵ Assessment of SPF-related aspects in this activity is based on Commission Recommendation 2006/647/EC, which is not legally binding. Enforcement measures by Member States are, however, grounded in the legally binding provisions of the Cosmetic Claims Regulation (EU) No 655/2013

also recognises a hybrid diffuse reflectance spectroscopy method (HDRS, EN ISO 23698:2024) as a further validated option.

In addition, markings and mandatory warnings on the packaging were checked in line with the EU laws, using a common checklist applied by all participating MSAs.

SAMPLING AND TESTING

OVERVIEW OF SAMPLED PRODUCTS

MSAs largely adopted a risk based sampling approach, prioritising products based on one or more risk indicators, such as a higher likelihood or potential impact of non compliance, or their novelty and widespread availability on the market.⁶

The sampled products covered a range of product types, including creams, lotions, sprays and sticks. Most products offered high or very high protection (49 high, 24 very high, 1 medium) and contained organic, mineral, or combined UV filters.

A total of 74 samples were collected, with 66 products (89%) sourced from physical stores, and 8 products (11%) from online sales channels.

Table 2: Distribution of samples by MSA and product type (n=74)

Country	Market Surveillance Authority	No. of samples
Austria	Austrian Agency for Health and Food Safety on behalf of Federal Ministry, Labor, Social Affairs, Health, Care and Consumer Protection of Austria	8
Finland	Finnish Safety and Chemicals Agency	5
Germany	State Institute for Chemical Analysis and Veterinary Diagnostics Karlsruhe	10
Latvia	Health Inspectorate	6
Lithuania	State Consumer Rights Protection Authority	6
Luxembourg	Ministry of Health and Social security (M3S) (Health Directorate – Division of pharmacy and medicines)	6
Malta	Malta Competition and Consumer Affairs Authority	6
Poland	State Sanitary Inspection - Chief Sanitary Inspectorate	6
Portugal	National Authority of Medicines and Health Products	9
Romania	National Institute of Public Health	8
Sweden	Swedish Medical Products Agency	4

⁶ Some MSAs indicated that results from previous years, including in silico screening or modelling tools, may inform risk prioritisation.

TESTING PROCESS

Samples were collected independently by each participating MSA between August and September 2025 and submitted for testing to a laboratory.

Testing was carried out between October 2025 and March 2026. Each sample was tested for three official standards. Two products in stick/lip balm format could not be tested using the *in vitro* SPF method due to

application constraints. Separate test reports were issued for each method, and the results were reviewed by the MSAs to determine non-compliance, risk level and follow-up measures. The results and comparison between the SPF determination methods were subsequently discussed at a dedicated laboratory meeting held in March 2026, involving MSAs, the laboratory, and a technical expert.

TEST RESULTS

OVERVIEW OF MAIN FINDINGS

Based on the individual test results and the applicable regulatory framework, MSAs assessed each product to identify instances of non-conformity.

Overall, 33 of the 74 products assessed (45%) were evaluated by MSAs as non conforming with respect to UV protection performance (SPF and/or UVA), triggering follow-up actions with the responsible person and other relevant national economic operators, if needed or involved. The results reflect the largely targeted nature of the sampling strategy, which was based on a risk-based approach whereby products considered more likely to present compliance issues were selected for testing.

These results should not be considered representative of the overall sunscreen market.

When evaluating borderline cases, confidence intervals were taken into account, and discussions at the laboratory meeting highlighted that an individual assessment was required in cases where different validated methods, or additional evidence provided by economic operators (responsible persons), produced diverging outcomes.

RESULTS

Figure 1 presents the results of laboratory performance testing for SPF and UVA protection, illustrating the proportion of conforming/compliant and non conforming/non-compliant results in relation to measured values and labelled claims. Statistical measurement uncertainty was taken into account by MSAs in their assessments.

Figure 1:
Products meeting or not meeting
UV protection performance
requirements (SPF/UVA) in relation
to labelled claims (n=74)

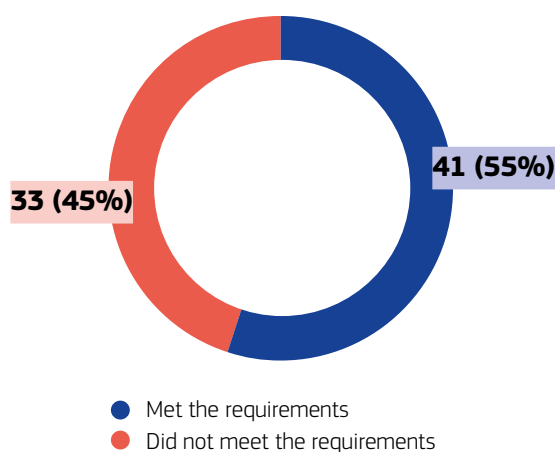
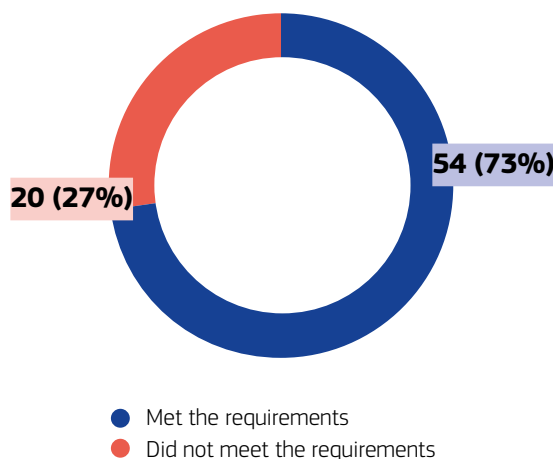


Figure 2 presents the results of checks on markings and mandatory warnings/precautions on package labels, as required by the EU Cosmetics Regulation and Commission Recommendation on sunscreen efficacy and claims.

A strong linear correlation between *in vivo* and *in vitro* SPF results ($r = 0.855$) was observed, indicating good overall agreement between the two methods and supporting the use of the *in vitro* method within its intended scope. The strongest correlation was observed for high-protection products, although *in vitro* values were generally slightly lower. The applicability of the *in vitro* method is currently limited to specific product formats (galenic forms).⁷

An important methodological consideration is that the *in vivo* SPF method is based on a physiological endpoint (erythema response), whereas the *in vitro* method measures a physical endpoint (UV transmission through a sunscreen film applied to a substrate). As a result, anti-inflammatory or soothing ingredients may reduce visible erythema without increasing actual UV protection.

Figure 2:
Products meeting or not meeting
mandatory warnings/precautions and
markings on package labels (n=74)



RISK EVALUATION AND MEASURES

RISK ASSESSMENT

Sunscreen products are intended to protect the skin against UV radiation, and their effectiveness relies on the accuracy of the information provided to consumers. Incorrect or misleading SPF or UVA claims may result in consumers receiving a lower level of protection than expected, potentially leading to increased UV exposure.

During this activity, MSAs assessed risks associated with non compliant products, considering the nature of the deficiency (e.g. product performance (SPF/UVA) or markings and warnings) and the extent of deviation from the claimed protection level. Particular attention was given to products intended for vulnerable groups (e.g. children or consumers with sensitive skin). Products with significant deviations were considered higher risk and subject to appropriate follow-up actions by MSAs.

⁷ EN ISO 23675:2024 currently applies to emulsion and alcoholic single phase sunscreen formulations and excludes powders and stick formats.

MEASURES

MSAs adopted follow-up measures proportionate to the identified risk. These corrective actions, requested from economic operators (e.g. responsible persons), most commonly consisted of product withdrawals, as well

as sales bans, destruction of products, recalls from end users, warning consumers, for example on [Safety Gate](#), and other measures, in line with national procedures and EU market surveillance practice.⁸

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

This activity provided practical insights into SPF compliance, UVA protection, and the use of validated SPF testing methods in market surveillance.

Testing also identified instances of non-conformity/non-compliance among the sampled products, including cases where the level of protection achieved did not fully correspond to the claims made, confirming the continued relevance of market surveillance activities and follow-up actions in this area.

The results confirmed that the *in vitro* SPF method shows a good correlation with the *in vivo* method and offers

clear ethical advantages by reducing the need for testing on human volunteers. For product types within its scope, the *in vitro* method can be prioritised over the *in vivo* method as a reliable approach for SPF determination.

These findings support the ongoing transition towards alternative testing methods that do not harm humans: While the *in vivo* method continues to be widely used, scientific progress and recent ISO standards have introduced validated alternatives, including *in vitro* and hybrid approaches.

RECOMMENDATIONS AND MESSAGES TO STAKEHOLDERS

The recommendations below relate solely to the comparison between the in vivo and the in vitro SPF method assessed within PSA 4. Other validated approaches, such as HDRS, were not evaluated and are therefore outside the scope of this analysis; however, the described advantages of alternative methods may also apply to HDRS.

Recommendations for economic operators (responsible persons)

- The EN ISO 23675:2024 SPF ***in vitro* test** method is a **reliable** and **reproducible** test method (within the scope of the ISO).
- It is recommended to use ***in vitro* testing for the determination of the SPF** during product development for claim substantiation. Where *in vitro* testing indicates that the formulation meets/exceeds the intended SPF label claim, *in vivo* testing is not required in consideration of ethical aspects. Where *in vitro* testing indicates that the formulation does not achieve the intended SPF claim, take action prior to market placement (for example, change formula, relabel claim, etc.).
- If an **anti-inflammatory** ingredient is present, opt for an additional *in vitro* testing in any case, as soothing ingredients might over-estimate UV protection *in vivo*. Take into account that *in vivo* and *in vitro* have different endpoints (physiological and physical).
- **Repeat the SPF test** for the same sunscreen product as part of **stability** checks (e.g. influence of different **storage** conditions, close to the end of shelf

⁸ The corrective measures are those provided by the MSAs by the deadline of 29 May 2026. While measures are continuing beyond this date as part of an ongoing process performed by the MSAs, a cut-off date was established for the purposes of reporting.

life, etc.), to verify that the claimed protection level remains consistent over time.

- If you adjust or change your formula, **re-test** the sunscreen product.
- Where a test method is updated, **re-test** the product to ensure continued alignment with the updated method.
- Choose a test laboratory which performs relevant **proficiency test studies** (“ring testing”) to determine the SPF and UVA of your products reliably.
- Consider the lower bound of the confidence interval of the SPF test when labelling your product, to ensure a high level of consumer protection.
- Ensure a clear connection between the test report and the product under inspection when providing requested documentation to MSAs (e.g. include formula ID or list of ingredients in the report).
- Be reminded that, before placing a sunscreen product on the EU market, it must comply with the EU Cosmetics Regulation (1223/2009) and the Cosmetic Claims Regulation (655/2013). It should also follow the European Commission Recommendation on the efficacy of sunscreen products and the claims made relating to them (2006/647/EC).

Recommendations for consumers

- Exposure to UV radiation, including UVB and UVA, poses risks to human health. Besides **primary sun protection measures** (shade, clothing, avoiding sun exposure at peak hours), use also sunscreen as **additional** protection.
- Choose a sunscreen with SPF and UVA protection suited to your skin type and the level of sun exposure.
- Read and follow the instructions on the package of your sunscreen product for correct use, e.g. how much product to apply. Apply and **re-apply** sunscreen **generously** and **evenly**.
- Note the opening **date on the sunscreen container** to respect its period after opening. Store in a cool, dry place, and avoid direct exposure of the product

to the sun. Do not use the product if its appearance (viscosity) or smell changes.

- Be aware that sunscreen formulation requires specialised expertise. **Do not attempt to prepare sunscreen products at home** (not DIY = do not do it yourself), as their protection level is not validated and insufficient efficacy may pose a risk to your health.
- UV filters must be assessed and authorised and therefore both mineral and chemical UV filters are safe and effective when used in compliance with EU regulation.

Recommendations for MSAs

- Carry out market surveillance of sunscreen products, including laboratory testing (preferably *in vitro*), documentary controls, and checks on labels. **In silico** testing is a suitable **screening** tool to predict the SPF, UVA protection factor, and critical wavelength.
- Choose a test laboratory which performs relevant proficiency test studies (“ring testing”) to determine the SPF and UVA of your products reliably.
- Verify that there is a clear connection between the test report provided by the responsible person and the product (e.g. check formula ID or list of ingredients in the report).
- Inform consumers about the benefits of sunscreen use and UV protection.

Recommendations for the European Commission

- Consider PSA 4 results in the revision of the 2006/647/EC Sunscreen Recommendation:
 - Take into account the results of the JACOP2025/PSA 4 testing campaign when **revising the Commission Recommendation 2006/647/EC on sunscreen efficacy and claims**, particularly with regard to the various validated SPF testing methodologies (EN ISO 24444, EN ISO 23675, EN ISO 23698).
 - The observed high level of correlation between *in vivo* and *in vitro* SPF test results supports further consideration of the *in vitro* method as a reliable tool for substantiating SPF claims.
- Consider introducing binding requirements at EU level addressing:
 - Repeated SPF testing when standard evolves.
 - Repeated SPF testing following formulation changes.
 - Repeated SPF testing as part of stability/durability verification.
- Given the limited availability of ISO/IEC 17025-accredited scopes for key sunscreen methods (EN ISO 24444, 23675, 23698, 24443), consider encouraging the development of harmonised **accreditation** scopes or guidance to support consistent implementation of these methods across laboratories.
- Consider the inclusion of an **expiry date** on the packaging of sunscreens in the context of the evaluation of the Cosmetics Regulation (EC) 1223/2009.
- Continue organising JACOP activities on testing sunscreen products.

Recommendations for standardisation organisation

- Extend the scope of the *in vitro* (EN ISO 23675:2024) test method to additional formulations and water-resistant claims.
- Clearly describe the limitations and appropriate use of the *in vitro* SPF method (EN ISO 23675:2024) within the standard to ensure consistent application.

Part 2

WHAT IS JACOP?

The JACOP initiative aims to organise Joint Actions on Compliance of Products in the EU and EFTA countries, fostering collaboration among Market Surveillance Authorities (MSAs). The primary objectives include conducting joint product testing, assessing risks and harmonising operational methodologies. Through open dialogues, knowledge-sharing, and engaging external stakeholders, the project contributes to a secure Single Market. Key focuses involve evaluating product risks, implementing timely measures and ensuring regulatory alignment.

JACOP 2025 INCLUDES 11 PRODUCT-SPECIFIC ACTIVITIES COVERING 9 SECTORS

PSAs test different types of products to assess their compliance with existing legislation and regulations and take appropriate actions. The products are selected and

collected by the market surveillance authorities involved and are examined using an agreed testing plan.



PSA 1
FERTILISERS



PSA 2
**INSULATING MATERIALS
IN CONSTRUCTION
PRODUCTS**



PSA 3
**HAZARDOUS
SUBSTANCES
IN GADGETS**



PSA 4
COSMETICS



PSA 5
RADIO TOYS



PSA 6
**CONSUMER
TEXTILE CLOTHING**



PSA 7
**LIFTS AND SAFETY
COMPONENTS OF LIFTS**



PSA 8
**GAS
APPLIANCES**



PSA 9
**PPE HELMETS
(PROFESSIONAL)**



PSA 10
**PPE HELMETS
(CONSUMER)**

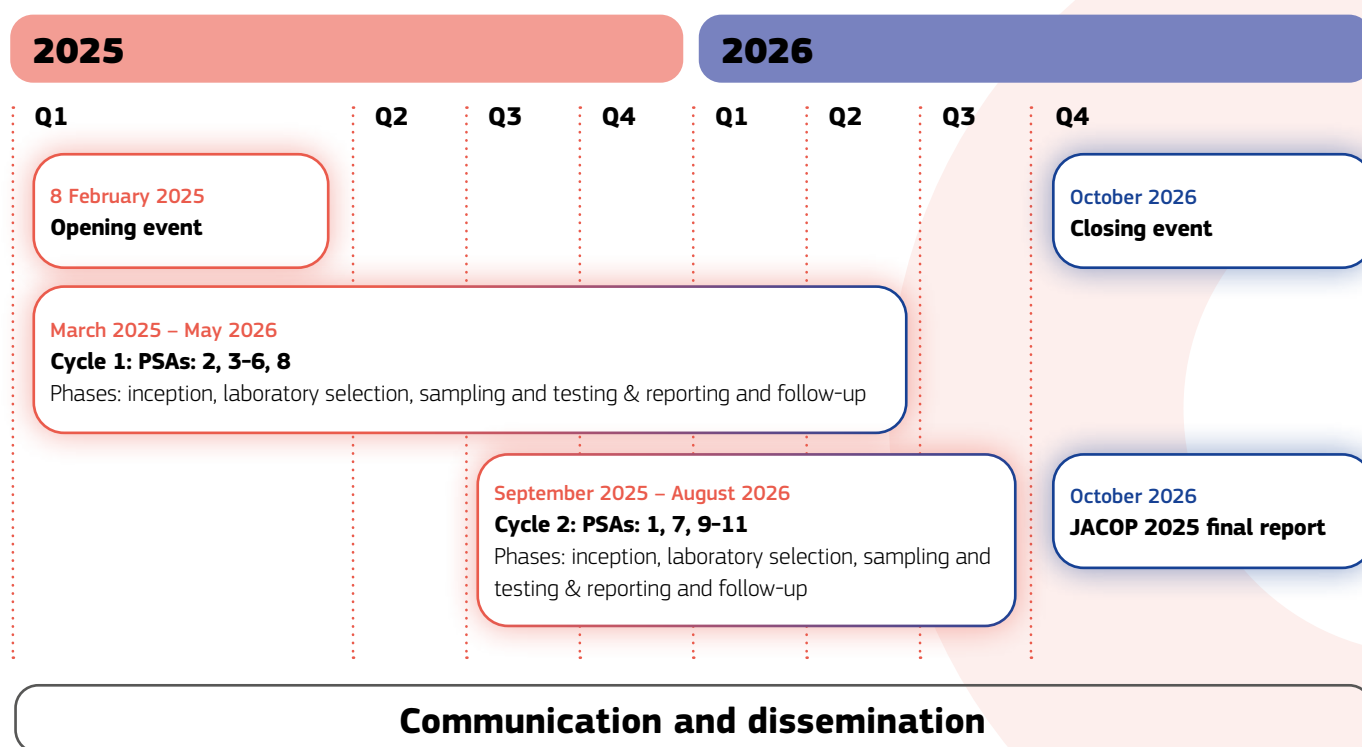


PSA 11
**PPE FOOTWEAR
(PROFESSIONAL)**

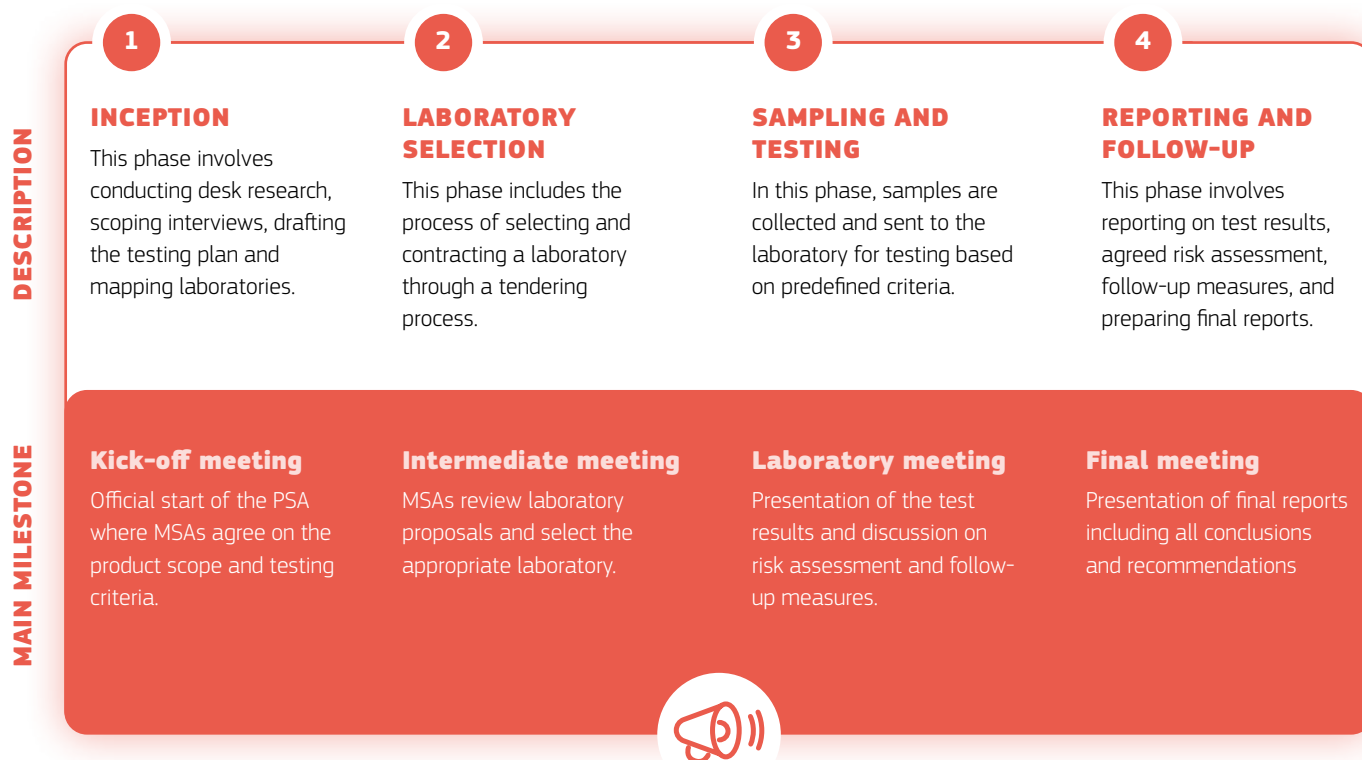
ROLES AND RESPONSIBILITIES



WORK PLAN AND TIMELINE



PROJECT PHASES



COMMUNICATION AND DISSEMINATION

Communication and dissemination activities involve raising product safety awareness among MSAs, consumers, and economic operators through targeted campaigns, media engagement, and influencer involvement, focusing on compliance education.

PROCESS



COMMUNICATION ASSETS

For all 11 PSAs:



Article summarising the main findings of the testing activity. The article includes at least 1 image.



One **social media** visual based on the infographics.



One-page infographic summarising the main findings of the testing activity.



One infographic and one social media visual covering the entire JACOP 2025 project.

These communication assets are available in 23 EU languages + Norwegian and Icelandic.

For 3 PSAs:

PSA 4 - Cosmetics, PSA 8 - Gas Appliances, PSA 10 - PPE Helmets (Consumer)



Short **video** for social media promotion.

COMMUNICATION CHANNELS

The communication assets are disseminated using:



National and specialised media across the EU27.



Online and social media platforms.



Influencers on social media.



MSAs' national communication channels.



JACOP 2025 newsletter – a four-issue series showcasing the campaign's progress, key milestones, and major achievements.

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