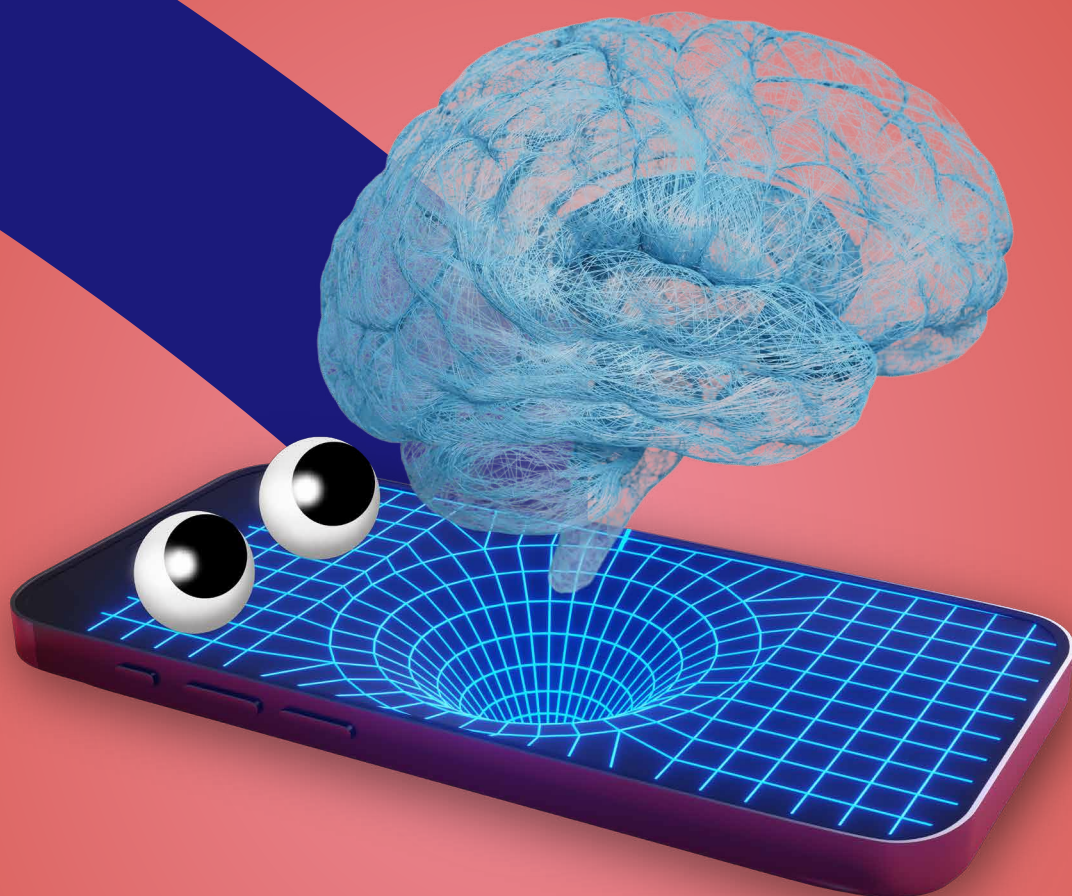




CASP 2025

HA – Mental health risks

Final activity report

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List of abbreviations

AI	Artificial intelligence
CASP	Coordinated Activities on the Safety of Products
DG JUST	Directorate-General for Justice and Consumers
EFTA	European Free Trade Association
EISMEA	European Innovation Council and SMEs Executive Agency
EO	Economic operator
EU	European Union
GDPR	General Data Protection Regulation
GPSR	General Product Safety Regulation
HA	Horizontal activity
IM	Intermediate meeting
KoM	Kick-off meeting
MSA	Market surveillance authority

Executive summary

Objectives

The overarching goal of the Coordinated Activities on the Safety of Products (CASP) project is to protect the health and safety of European consumers by supporting market surveillance authorities (MSAs) from EU/EFTA countries to better coordinate their activities. The CASP 2025 horizontal activity on mental health risks aimed to

address gaps in the assessment of mental health risks posed by new technology products under the General Product Safety Regulation (GPSR). The activity facilitated exchange among MSAs and consolidated cross-sector evidence to support the development of potential approaches to formalised risk assessments.

Outcomes

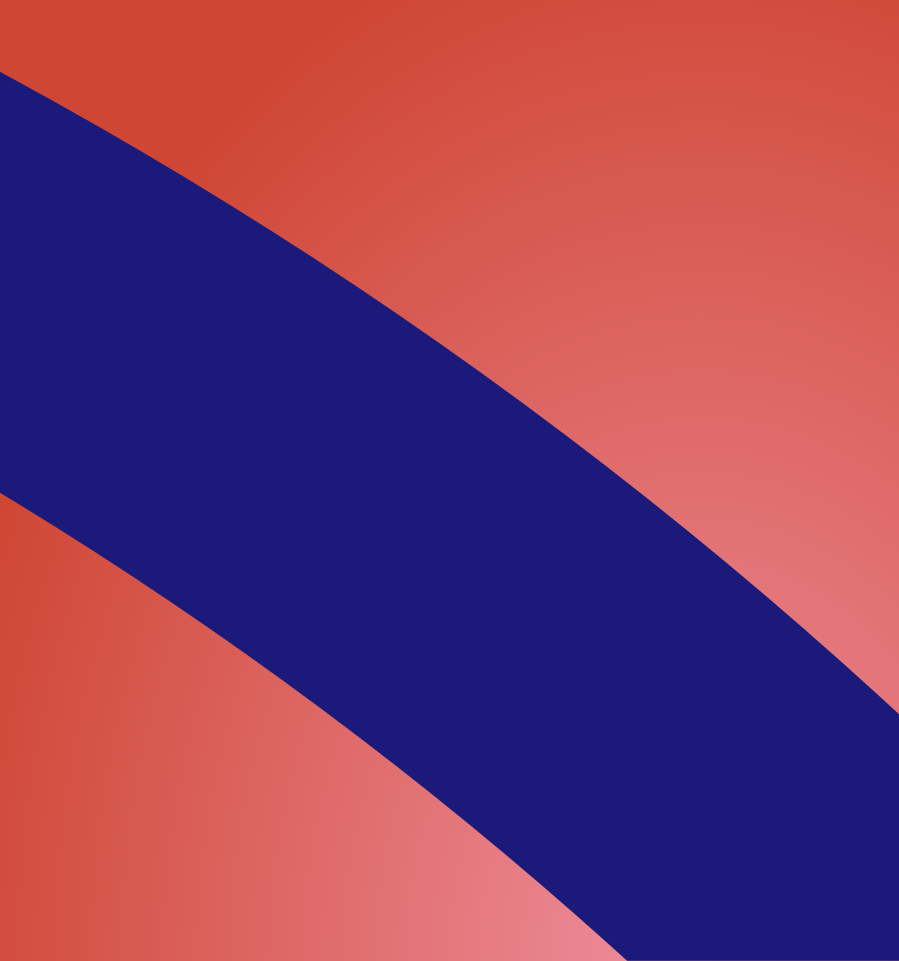
The outcome of this activity was a **concept paper** with recommendations and possible risk assessment approaches, drawing from legal and scientific expertise and reinforced by stakeholder inputs and practical case

studies. The concept paper aims to act as a reference point which MSAs can employ when considering the possible mental health risks of a product, and a building block upon which future guidance can be developed.

Conclusions

The activity aimed to address key market surveillance issues arising from the novelty of the topic, including the currently limited experience and resources available to MSAs for risk assessment. Clear guidance, education on risk pathways and practical exercises are crucial to start performing mental health risk assessments in practice.

Throughout the activity, the concept paper was developed with the aim of bringing together expertise from different fields to comprehensively lay out the evidence linking new technology products, their features, and patterns of use with adverse mental health outcomes.



Part I

Activity overview

Introduction and main objectives

The GPSR requires that products placed or made available on the EU market do not pose risks to consumers' health and safety, including risks to psychological well-being¹. In this context, MSAs are increasingly confronted with questions related to the mental health impacts of new technology products. These risks may stem from product functionalities, design choices or interaction patterns and often manifest in ways that are less immediate or tangible than traditional physical safety risks.

Assessing mental health risks poses specific challenges for MSAs. Existing product safety tools, testing methods and standards are generally not designed to capture such risks and practical experience in this area remains limited. As a result, MSAs may face uncertainty when determining how mental health considerations should be identified, assessed and addressed within the framework of product safety enforcement, which may lead to diverging approaches across Member States and hesitancy in addressing these risks.

The CASP 2025 horizontal activity (HA) on mental health risks aimed to support MSAs in addressing these challenges by providing a structured forum for exchange and reflection. The activity focused on developing a shared understanding of how mental health risks related to new technology products can be approached in practice, taking into account legal requirements, emerging scientific insights and the realities of market surveillance work.

The overall objective of the activity was to support MSAs in developing a shared foundational understanding of how mental health risks may arise in relation to product use and how such risks can be considered in practice, given the lack of standards and limited guidance available on this topic. The specific objectives of the activity were to (i) clarify key concepts and considerations relevant to the identification of mental health risks in the context of product safety, and (ii) explore possible approaches for MSAs to integrate such considerations into their existing assessment and enforcement activities. The primary outcome of the activity is a concept paper, intended to serve as a reference document that supports MSAs in navigating this evolving area and contributes to more informed and coherent approaches across the EU.

¹ GPSR, Article 3(2) and GPSR, Recital 19

Participating market surveillance authorities

Table 1 - List of participating MSAs

#	Country	Name of the authority (English)
1	 Belgium	Federal Public Service Economy - Directorate General Quality and Safety
2	 Cyprus	Department of Labour Inspection
3	 Czechia	Czech Trade Inspection Authority
4	 Denmark	Danish Safety Technology Authority
5	 Estonia	Consumer Protection and Technical Regulatory Authority
6	 France	Directorate-General for Competition, Consumer Protection and Fraud Control
7	 Germany	Government of Upper Bavaria - Trade Supervisory Authority
8	 Germany	Saxony State Directorate – Division 56
9	 Hungary	Ministry for National Economy
10	 Ireland	Competition and Consumer Protection Commission
11	 Italy	Pistoia-Prato Chamber of Commerce
12	 Latvia	Consumer Rights Protection Centre
13	 Lithuania	State Consumer Rights Protection Authority
14	 Malta	Malta Competition and Consumer Affairs Authority
15	 Slovenia	Market Inspectorate of the Republic of Slovenia
16	 Spain	Ministry of Social Rights, Consumer Affairs and Agenda 2030

Main activities and outcomes

Scope of the activity

The scope of the CASP 2025 horizontal activity covered mental health risks of new technology products. Given that there is no legal definition of what constitutes a new technology product, participants focused the product scope on consumer products with artificial intelligence (AI) or internet-connected functionalities, such as AI

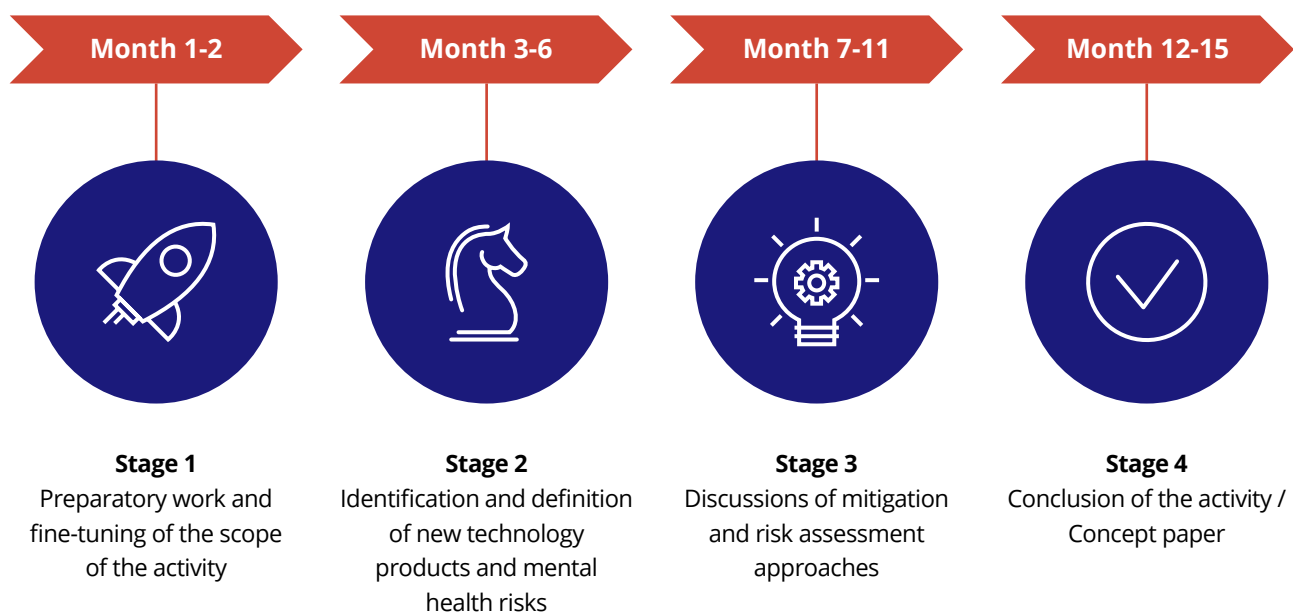
chatbots or AI-powered toys and games. Rather than focusing narrowly on specific products, the activity explored these broad categories of technology products and examined the risk pathways of specific design features found in a variety of different products.

Work approach

The activity was designed as a **learning oriented exercise** to raise awareness about mental health as a product safety concern, explore relevant legal and scientific perspectives and identify key challenges and considerations that may inform future approaches and follow-up work at EU level.

The work approach for this activity followed a four-stage approach outlined in Figure 1 below.

Figure 1: Horizontal activity work approach



Stage 1: Preparatory work

The first stage focused on gathering background information and fine-tuning the scope of the activity. This included a scoping interview with the technical expert and desk officers from the Directorate-General for Justice and Consumers (DG JUST) at the European Commission, to identify the priorities and expectations for the activity. This was followed by a preliminary consultation with the participating MSAs to collect information about their experiences, preferences and challenges they face regarding the assessment of mental health risks.

The first stage concluded with a kick-off meeting (KoM) in June 2025, where the project team presented the activity's scope, objectives and legal and scientific context of the activity and the outcome of the preliminary consultation. During the KoM, the MSAs were invited to join an interactive brainstorming session to share their needs and expectations for the concept paper, to clarify how it would be of the most use for them.

Stage 2: Identification and definition of products and risks

The second stage of the activity commenced with developing the structure of the deliverable. Based on the feedback collected in the KoM, the project team drafted the outline of the concept paper and validated it with the MSAs through collaborative, online Wiki consultations. Throughout the second stage, the project team contacted and interviewed several stakeholders, including designers of new technology products, academics, advocacy organisations and educators, to gather various perspectives about the mental health risks of new technology products and feed into the development of the concept paper. Throughout the second stage, the project team and technical experts drafted the background

chapters of the concept paper, including the introduction, legal context and scientific background. Prior to the first intermediate meeting (IM), the draft concept paper was shared with the MSAs for review.

During the first IM, the first draft of the concept paper was presented and an interactive session using a collaborative online tool took place to collect feedback on the value of the first chapters, and to gather input on expectations and priorities for the remaining chapters. Three stakeholders were invited to present during the IM, to share their insights and perspectives about the mental health risks of new technology products.

Stage 3: Mitigation and risk assessment approaches

The third stage of the activity was centred around developing approaches for risk assessment and recommendations for risk mitigation. During this stage, the concept paper chapters on risk assessment approaches and insights from economic operators were drafted. Prior to the second intermediate meeting, the second draft of the concept paper was shared with MSAs on Wiki for review.

The aim of the second IM was primarily to fine-tune the recommendations and approaches for the assessment

of mental health risks. Two stakeholders presented their work during this meeting, feeding into the discussion during the second half of the meeting. The second draft of the concept paper was presented, and breakout sessions were held with the MSAs to discuss their understanding of the proposed risk assessment approaches and the alignment with their expectations. An open discussion was held to review the concept paper as a whole and identify any remaining gaps to address in the final version.

Stage 4: Conclusion of the activity

During the fourth stage, the objective was to finalise the concept paper and obtain MSAs' feedback and approval. Prior to the final meeting, the project team shared the revised draft of the concept paper with the MSAs and consulted them for a final round of review. During the final meeting, additional feedback and comments were discussed and an interactive game session was held. During this session, MSAs applied the knowledge

gathered in the concept paper to debate the risks of one selected new technology product and discuss how these can be eliminated, mitigated, or warned about. Following the final meeting, MSAs were given several days to finalise their comments on the concept paper. After integrating the feedback, the project team shared the final version of the paper with the MSAs on the Wiki for their validation.

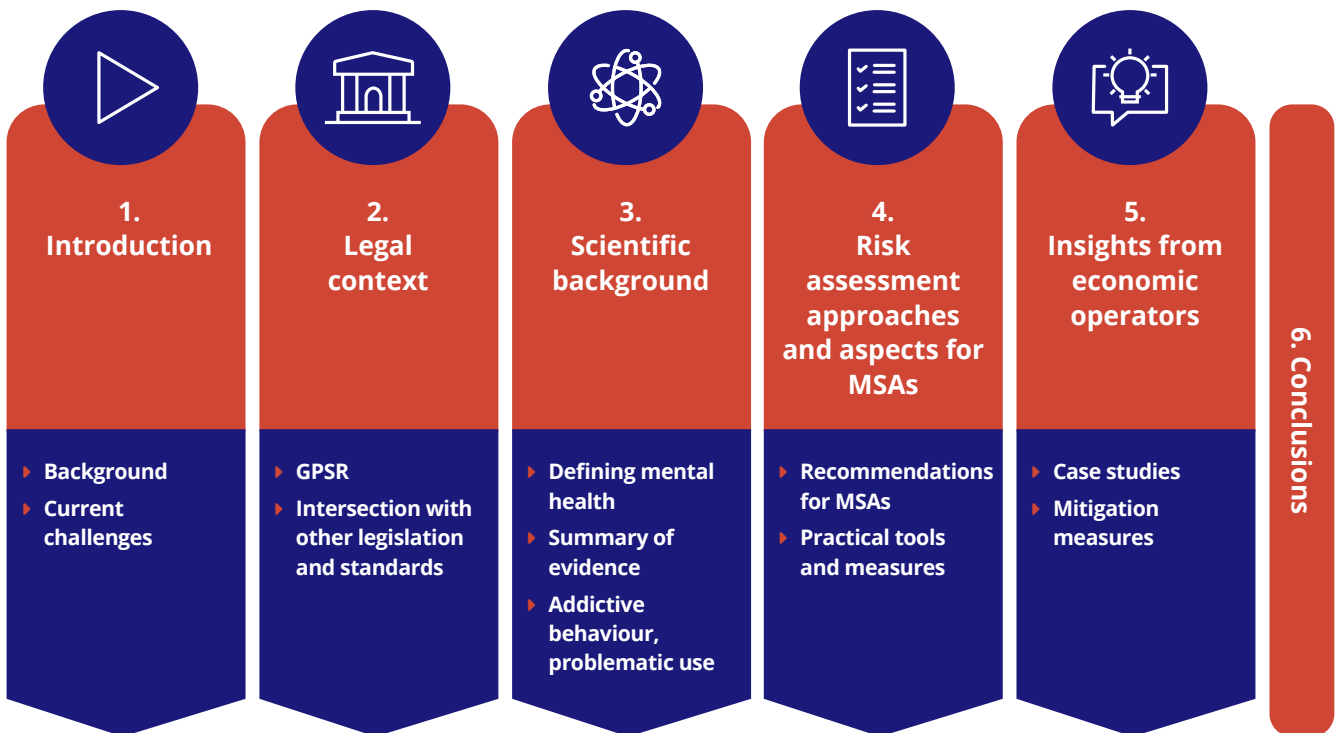
Deliverable

A concept paper was developed as a reference point for MSAs when considering a risk assessment of a new technology product suspected of having negative impacts on users' mental health. The concept paper aimed to consolidate legal, scientific and stakeholder evidence

to map the current knowledge about the mental health risks of new technology products and how MSAs can apply this in practice in formal risk assessments.

The concept paper is divided into six chapters, summarised below.

Figure 2: Concept paper structure



1. Introduction

This chapter outlines the scope of the paper and the main challenges that MSAs face in assessing mental health risks due to:

- ▶ a lack of **experience and resources** for mental health risk assessment;
- ▶ unclear **definitions** on what constitutes a mental health risk;
- ▶ rapid **technological developments** that outpace the development of safeguards or regulatory interventions;
- ▶ the broad **range of products** with potential mental health risks; and
- ▶ the highly **individual and context-specific** mental health impacts of the products.

2. Legal context

This chapter includes the legal definitions of what constitutes a product and a risk, and how mental health risks posed by new technology products fit within those definitions. The chapter also covers the intersection of the GPSR with other legislation on this topic, including the AI Act, Digital Services Act, and the General Data

Protection Regulation (GDPR), among others. It provides an overview of standards that may be applied by analogy to new technology products to assess their safety in relation to mental health.

3. Scientific background

The scientific background chapter summarises current research on the effects of technology on mental health, looking particularly at the evidence linking technology products to problematic use patterns. It describes specific design features and affordances, and how these

have been linked to adverse mental health outcomes, and considers moderating factors which can exacerbate or alter these effects on mental health. The limitations and challenges of existing evidence are discussed, and remaining research gaps are identified.

4. Risk assessment approaches and aspects for MSAs

The fourth chapter outlines recommendations for MSAs to approach mental health risk assessments. The evidence available to MSAs is often incomplete or uncertain and plausible harms are not evident. The chapter outlines some instruments and general approaches that MSAs can use as a starting point for

mental health risk assessments. This includes several clinical tools that MSAs can reference to understand how mental health can be evaluated and quantified, as well as a multi-source evidence strategy to guide MSAs through the process of gathering evidence and identifying risks to the best of their ability, given the inherent limitations.

5. Insights from economic operators

The fifth chapter focuses on case studies of suicides and homicides linked to chatbots or other new technology products, and considers the extent to which harmful and addictive features linked to mental health impacts can be removed or mitigated. It highlights actions which economic operators (EOs) can and should take to mitigate

the risks of their products, such as limiting human-like features and enabling protective settings by default. This chapter includes a practical case study on an online gaming platform², to demonstrate the complexities involved in assessing the mental health risks of a specific technology product in practice.

6. Conclusions

The conclusion highlights that the concept paper serves as a first reference point for MSAs to consider for mental health risk assessments, recognising that it is not a step-

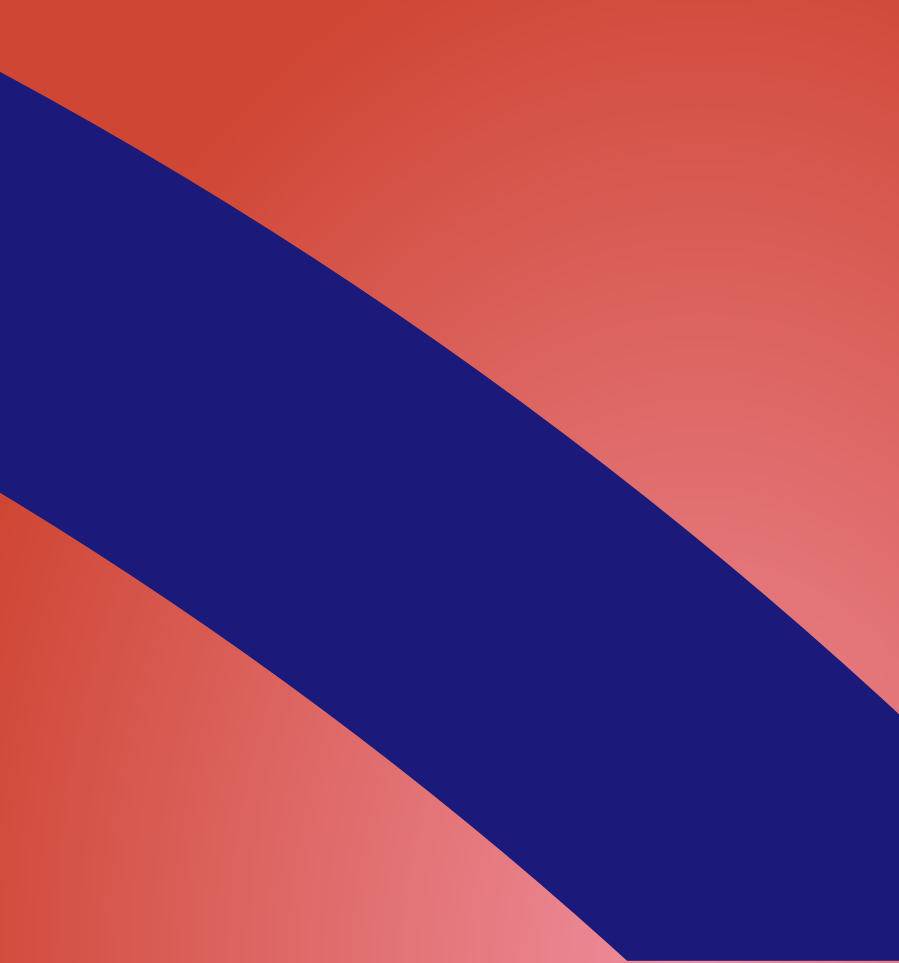
by-step guidance document to follow. It is a foundation on which such guidance and practical experience can be built in the future.

Conclusions

Assessing the mental health risks of new technology products poses several challenges for MSAs, given the novelty and complexity of the topic and the products involved. Neither the scientific evidence nor the legal framework and guidelines for MSAs are clearly defined, and the psychological aspects of risk assessment are new territory for MSAs, who are generally used to assessing the physical health and safety risks of products. Further activities and cooperation are needed to continue laying the groundwork for the development of comprehensive and harmonised guidance for risk assessment.

By gathering available scientific evidence, legal expertise and insights from a wide range of stakeholders, this activity was able to map the current landscape of knowledge and potential pathways for MSAs to consider. It provided MSAs with a starting point for risk assessment, from which future step-by-step guidance can be developed, once MSAs have attempted assessments and obtained practical experience.

² Roblox



Part II

What is CASP?

The Coordinated Activities on the Safety of Products (CASP) enable market surveillance authorities from European Union / European Free Trade Agreement

countries to cooperate and reinforce the safety of products placed on the Single Market.

CASP 2025 includes two product-specific activities and one horizontal activity.

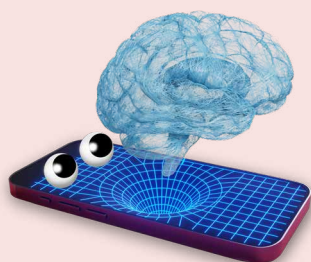
Participants in the product-specific activities test the jointly selected products sampled on their respective national markets. The products are tested in accredited laboratories in the EU/EFTA according to the commonly agreed testing criteria.



PSA 1
Chemicals



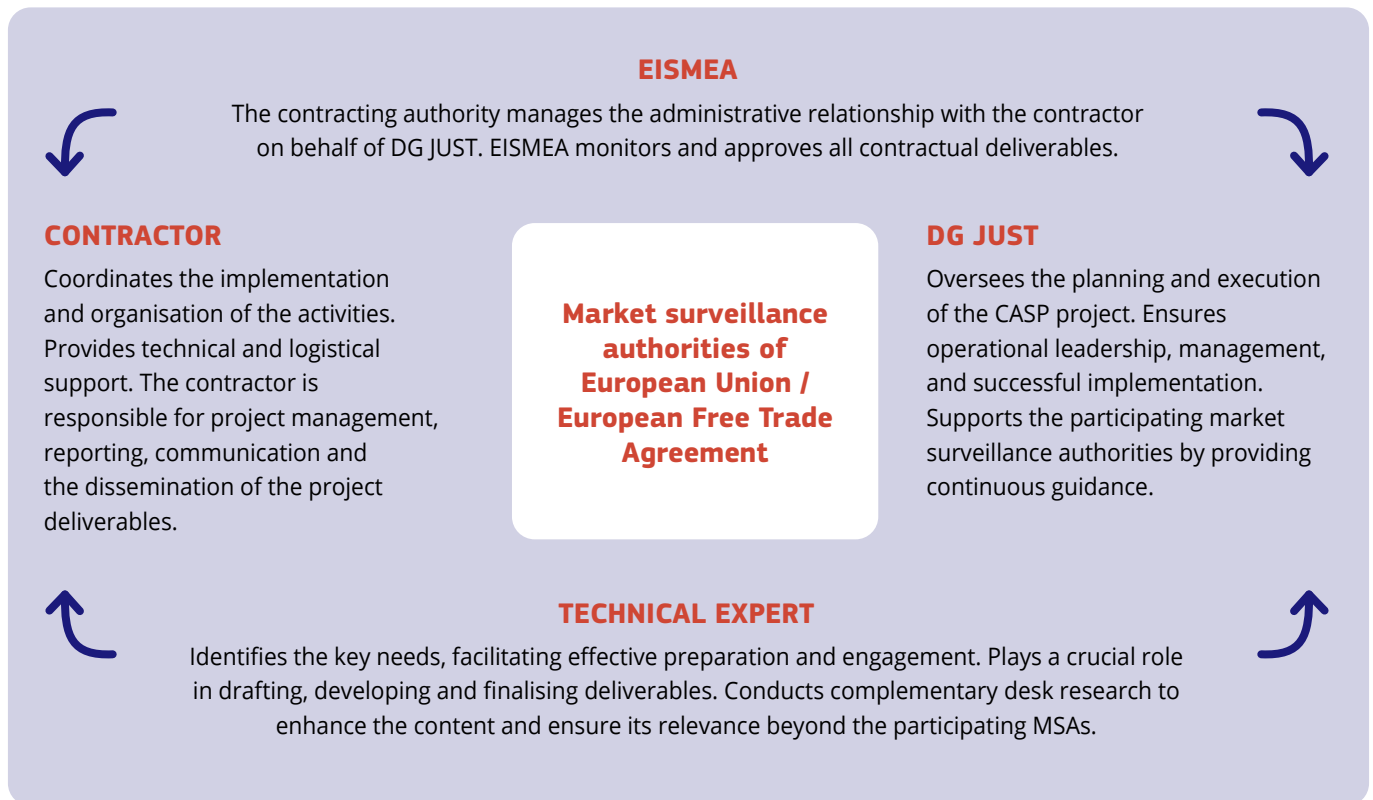
PSA 2
Child bicycle seats



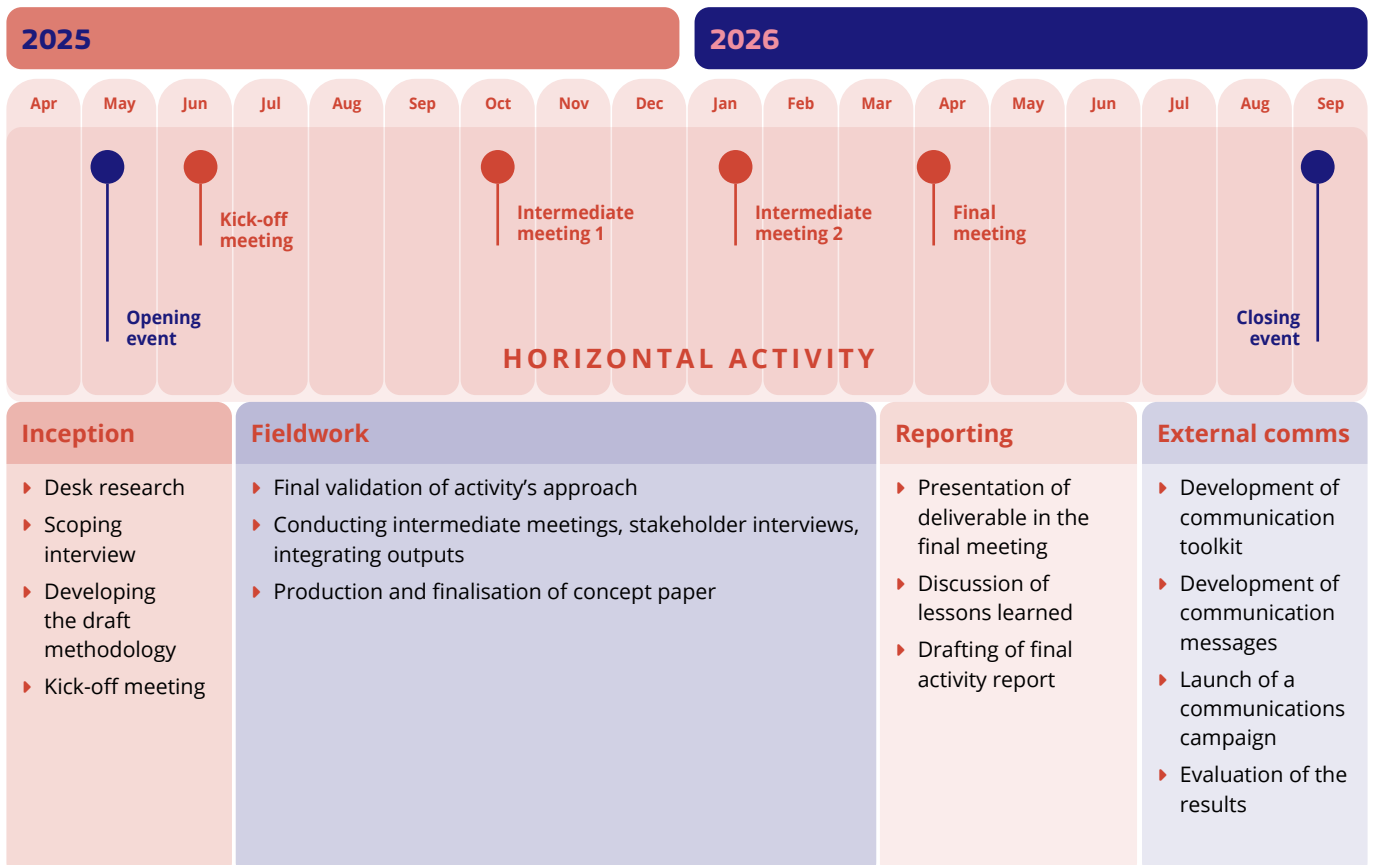
HA
Mental health risks

Horizontal activities provide a knowledge-exchange forum for market surveillance authorities. With the guidance of technical experts in the relevant fields, the participants develop common approaches, procedures and practical tools for market surveillance.

Roles and responsibilities



Horizontal activity work plan



Overview of the horizontal activity approach

0 Pre-CASP process

DG JUST conducts a priority setting exercise with market surveillance authorities to select topics of common interest prior to the launch of each CASP project. The CASP 2025 horizontal activity reflects the interest of market surveillance authorities in receiving guidance on the identification and assessment of mental health risks of new technology products.

1 Fine-tuning of activity objectives

The fine-tuning of activity objectives involves a comprehensive process to ensure alignment with the needs and expectations of market surveillance authorities. This process begins with conducting surveys, desk research, and a thorough needs assessment to gather insights from market surveillance authorities about their specific needs, challenges, and priorities, identifying key areas of focus for the activity. A Kick-off meeting is then organised to discuss preliminary objectives and gather feedback, providing a platform for open dialogue and refinement of objectives. Throughout this process, close collaboration with market surveillance authorities through Wiki consultations ensures that the refined objectives are realistic, achievable, and aligned with their operational goals.

2 Development of methodology

The development of the methodology begins with an initial draft, which is built upon and refined through two intermediate meetings and ongoing Wiki consultations with market surveillance authorities. The draft is continuously refined and adjusted based on feedback from market surveillance authorities, ensuring that it is practical and tailored to their specific needs. This iterative process ensures that the final methodology is comprehensive and well-aligned with the objectives and needs of the MSAs.

3 Development of the Deliverable

The deliverable is co-developed with the market surveillance authorities to ensure relevance. Incorporating input from market surveillance authorities, the deliverable, the concept paper on mental health risks of new technology products, is based on the agreed methodology and developed with the guidance of the technical expert. This collaborative approach ensures that the deliverable is tailored to the specific needs and challenges identified by the MSAs, enhancing its effectiveness and impact.

4 Finalisation of outcomes, lessons learned and recommendations

The final step involves validating the outcomes, discussing lessons learned, and formulating recommendations. This process ensures that the project delivers valuable insights and actionable guidance for future activities. Presenting the final outcomes in the final meeting ensures they meet the objectives and expectations set during the project. Finally, drafting final reports that include recommendations based on the validated outcomes and lessons learned provides a roadmap for future improvements and initiatives.

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Publications Office
of the European Union

Luxembourg: Publications Office of the European Union, 2026

ISBN 978-92-68-38106-9
doi:10.2838/1862408