EN

European Commission

CASP2021

Coordinated Activities on the Safety of Products

Risk assessment and management

Final Report

Justice and Consumers

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List of abbreviations

ABBREVIATION	DESCRIPTION
CASP	Coordinated Activities on the Safety of Products
EC	European Commission
EEA	European Economic Area
EISMEA	European Innovation Council and SMEs Executive Agency
EO	Economic operator
EU	European Union
GPSD	General Product Safety Directive (2001/95/EC)
HA	Horizontal activity
ICSMS	Information and Communication System for European Market Surveillance
IM	Intermediate meeting
KoM	Kick-off meeting
MS	Member State(s)
MSA	Market surveillance authority
RA	Risk assessment
RAG tool	Risk Assessment Guidelines tool
RAPEX Guidelines	Commission Decision (EU) 2019/417
Safety Gate	Rapid alert system for dangerous non-food products

Executive summary

Objectives of the activity

The Coordinated Activities on the Safety of Products (CASP) projects enable all 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.

The CASP 2021 risk assessment and management (RAM) horizontal activity (HA) focused on increasing consistency in the risk assessment (RA) and risk management of non-food consumer products across EU/EEA MSAs by exchanging views and best practices. In doing so, it built on previous CASP activities that sought to harmonise RAM approaches by providing guidance on injury scenarios, the estimation of probabilities, and risk management strategies[1].

More specifically, the 2021 RAM HA had the following objectives:

- map risks and areas that are challenging to assess and manage for MSAs;
- share strategies and tools to overcome these challenges through case-solving workshops;
- discuss difficult cases and share best practices by preparing guidance documents on RA and risk management.

Outcomes

Case-solving workshops

Two case-solving workshops were organised in which MSAs discussed both RA and risk management challenges based on a selection of case studies with the technical expert.

Guidance document on risk assessment

A guidance document on common risk assessment challenges and tools to overcome them was developed to provide MSAs with guidance on how to develop injury scenarios and estimate probabilities.

Guidance document on risk management

A second guidance document on risk management was prepared, providing MSA with tools and strategies to overcome risk management challenges and help to decide on corrective measures.

Conclusions and recommendations

The RAM HA provided an important forum for participating MSAs to discuss challenges and best practices related to RA and risk management. The discussions helped identify areas in which MSAs needed more assistance so that the guidelines could include needs-based tools and strategies to overcome common challenges. Based on the discussions held during the meetings of the activity, a number of recommendations were formulated.

For consumers

- Check Safety Gate before purchasing a product.
- Check for information about unsafe or defective products on MSA websites.

For economic operators (EOs)

- Use the RAG tool to assess risks associated with your products.
- Cooperate with MSAs on RAM.
- Be aware of your obligations under the applicable legislation.
- Have a corrective action plan in place to mitigate and eliminate the risks.

For national authorities

- Continue the exchange of views and best practices on difficult RA and risk management cases to increase consistency in approaches.
- Disseminate the CASP 2021 results.
- Identify issues related to emerging risks associated with novel products

[1] FOOTNOTE LINK TO BE RECEIVED

1. Overview of the activity

1.1 Introduction and objectives

According to the General Product Safety Directive (2001/95/EC) (GPSD), a product must be safe when it is used under reasonably foreseeable conditions over the entire lifetime of the product. Therefore, when assessing whether a product poses a risk, the assessment should be based on the harmonised and reproducible RA principles laid down in Decision (EU) 2019/417 (the RAPEX Guidelines) [2].

This activity focused on increasing consistency and harmonising the RA and risk management of non-food consumer products across EU/EEA MSAs by exchanging views and best practices and providing MSAs with guidance on how to overcome common challenges.

More specifically, the RAM HA had the following objectives:

- map risks and areas that are challenging to assess and manage for MSAs;
- create strategies and tools to overcome these difficulties through a series of case-solving workshops;
- discuss difficult cases and share best practices by preparing two guidance documents on performing RAs and managing risk that offer advice on identifying injury scenarios, estimating risk probabilities, and deciding on suitable corrective actions.

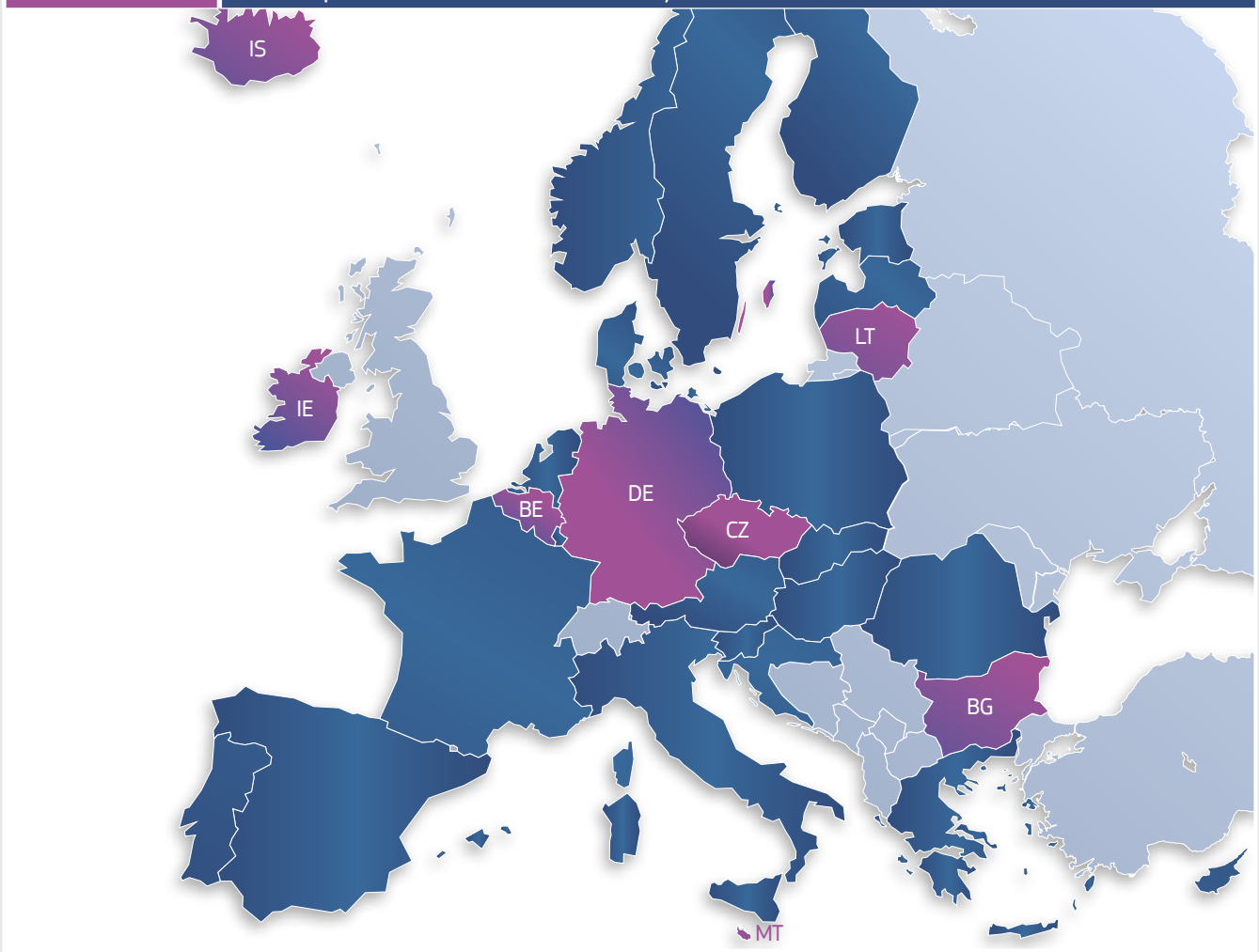
[2] The GPSD applies to products intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them (consumer products). It applies to these products when there are no specific provisions with the same objective in the rules of EU Law governing the safety of the products concerned.

1.2 Overview of participating MSAs

A total of 10 MSAs from 7 EU Member States (MS) and 1 EEA country participated in the RAM HA, as illustrated in the image below.

Table 1 - **Participating MSAs**

COUNTRY	MSA
Belgium	Federal Public Service Economy – Directorate-General Quality and Safety
Bulgaria	State Agency for Metrological and Technical Surveillance
Czechia	Czech Trade Inspection Authority
	Ministry of Industry and Trade
Germany	Trade Inspection office of the State of Bremen
	Government of Upper Bavaria - Trade Inspection Office
Iceland	The Housing and Construction Authority
Ireland	Competition and Consumer Protection Commission
Lithuania	State Consumer Rights Protection Authority
Malta	Malta Competition and Consumer Affairs Authority



2. Main activities and outcomes

2.1 Scoping of the activity

To prevent dangerous products from causing injuries to European consumers, MSAs take corrective risk management actions based on the outcomes of test results and/or RAs. Robust RAs are key to taking the most appropriate and effective corrective measures in order to mitigate the risk of injury and protect consumers.

Risk assessment challenges

RAs determine the likelihood of a hazard associated with a product resulting in a particular injury. This involves the identification of the injury severity (related to a specific hazard) and the probability that consumers will be injured by that hazard (exposure to the hazard). The subjective nature of determining the injury scenario and the probabilities, and the many (unknown) variables, make the RA process challenging for MSAs. To avoid arbitrary judgments, RAs need to be based on a robust rationale and clearly explain any assumptions made in the process. While the RAPEX Guidelines lay down basic RA principles and provide guidance on how to perform assessments, certain risks and elements of the RA process require more attention in order to increase the consistency of MSAs' assessments and ensure that risks presented by products are interpreted and managed consistently across the EU/EEA.

Hazard groups that have been identified as particularly challenging to assess for MSAs include:

- **fire and explosion**
- **radiation**
- **chemical risks**[3]
- **risks posed by novel products.**

Each group contains specific risks that need to be identified as the first step of an RA. Reoccurring challenges faced when identifying particular hazards and justifying the assumptions made in the development of injury scenarios include:

- **missing data and test reports;**
- **a general lack of expertise on certain risks and product groups.**

In the absence of the relevant expertise and information, MSAs need to make estimations and assumptions. This may decrease their confidence in their assessments and lead to significant uncertainty about the level of risk presented.

Risk management challenges

Risk management follows the RA process and aims at reducing or eliminating risk. While the risk outcome of the RA informs the decisions taken as part of risk management, risk management is about deciding the most appropriate action to take in order to reduce or eliminate consumers' exposure to a hazard. This requires MSAs to take a number of variables into account.

Corrective actions are a key part of risk management. Measures to mitigate or reduce the risk may be conducted either voluntarily by the EO or be required by MSAs. The most appropriate and proportionate corrective action will depend on the specific risk posed by the product, its location in the supply chain, the consumers who use it, and the most effective way to reduce or eliminate the exposure to the risk. Having to take all relevant variables into consideration can make it challenging for MSAs to decide on the appropriate risk management strategy. Low and medium risk products can pose particular challenges as the appropriate corrective actions depend on many factors and often require close collaboration with manufacturers. Working with EOs and Online Marketplaces to enforce measures is another challenging area for MSAs.

Strategies and tools developed in the activity

Risk assessment and risk management can be complex tasks, however appropriate strategies and tools can support MSAs during this process. Within the scope of the activity, MSAs discussed challenging cases and, based on this discussion, produced guidance documents that include tools and strategies to overcome common challenges.

[3] Chemicals have already been discussed in the CASP 2020 project, resulting in guidance on the estimation of probabilities and management of chemical hazards. The chemical risks discussed during CASP 2021 are focusing on effects of specific chemicals that have not previously been covered. FOOTNOTE LINK TO BE RECEIVED.

2.2 Working approach

In order to provide further guidance to MSAs and increase the consistency of RAs and risk management actions, the RAM HA was organised around three main deliverables:

- a guidance document identifying the risks that pose the most assessment challenges and the tools to overcome these challenges;
- a compilation of case studies of challenging risks included in the guidance document on RA (to be discussed in dedicated sessions during the HA);
- a guidance document on the management of identified risks.

The compilation of case studies and the development of the guidance documents took place in close cooperation with MSAs to ensure that the discussions of both the challenges and the potential solutions were based on their priorities and needs. During the activity's kick-off meeting (KoM), the MSAs discussed and selected the most challenging risks to focus on:

- fire and explosion
- radiation
- chemical risks
- risks posed by novel products.

Following the KoM, case studies focusing on the four hazard groups were collected. MSAs submitted challenging RA cases via the Wiki; these were further complemented by case studies chosen from Safety Gate notifications by the technical expert. The case studies were used to explore the main challenges MSAs have in relation to RAs.

During the first intermediate meeting (IM), the MSAs jointly discussed and completed an RA for each of the products with the help of the technical expert. Thanks to these discussions, the Contractor and the technical expert were able to identify the main challenges associated with each hazard that the guidance document should focus on. During the meeting the MSAs also discussed current best practices and other potential solutions that could be included in the guidance document. Based on the selected risks and the discussions on the case studies, the technical expert started developing the first guidance document on RA (which was presented during the second IM). The MSAs were encouraged to comment on the document during the meeting and to provide any additional feedback via the Wiki.

A similar process was followed to develop the guidance document on risk management. After several interviews and a survey on specific risk management challenges had been conducted, the second IM focused on discussing appropriate risk management actions to mitigate and eliminate identified risks. Following the discussion, the MSAs were presented with the proposed structure for the guidance document on risk management. The exchanges with the MSAs during the second IM helped the technical expert to tailor the guidance document to their needs. Both draft documents were presented during the final meeting, during which the MSAs could share their comments and feedback.

1

KoM

- Joint decisions on the final activity scope by MSAs
- Discussion of difficult RA cases experienced by MSAs
- Selection of most challenging risks to discuss during the workshops

2

Collection of challenging RA cases

- Collection of challenging case studies from MSAs experience via the Wiki platform

3

1st IM (case-solving workshop)

- Discussion and joint RAs on challenging risk cases
- MSAs' validation of the structure of the RA guidelines

4

Drafting of guidance document

- Based on the discussion on the case studies, the first draft of the RA guidelines is prepared by the technical expert
- MSAs provide feedback via the Wiki platform

5

Collection of risk management challenges

- Online survey and interviews with MSAs to collect risk management challenges

6

2nd IM (case-solving workshop)

- Presentation of the guide on risk assessment
- Discussion on risk management challenges
- MSAs' validation of the structure of the risk management guidelines

7

Drafting of guidance document

- Based on the discussion during the 2nd IM, the first draft of the risk management guide is prepared by the technical expert
- MSAs provide feedback via the Wiki platform

8

Final meeting

- Presentation of the final guidance documents

9

Reporting

- Wrap-up of the activity by incorporating final changes in the guidance documents and producing the HA final report

2.2.1 Development of the compilation of risk assessment case studies and the guidance document

The first guidance document was developed to support MSAs in the development of RAs, specifically focusing on:

- identifying the hazards and risks that pose the most assessment challenges for MSAs;
- providing guidance on these risks and hazards;
- identifying tools and strategies to overcome them.

The guidance document explores RA challenges through eight case studies (selected by MSAs and the technical expert) based on the four challenging hazards identified in the activity's KoM.

HAZARD GROUPS	CASE STUDIES
Fire and explosion	1. Overheating 2. Flammable substances
Radiation	3. Ultraviolet radiation 4. High intensity electromagnetic fields (EMFs)
Chemical risks	5. Hazardous solids or fluids 6. Hazardous gas
Risks posed by novel products	7. Internet of things (IoT) 8. Drones

Based on discussions with the MSAs, the guidance document includes tools and strategies to minimise subjectivity and overcome common challenges (such as the lack of expertise and test reports) faced during RAs. As well as providing information on how to find reliable data and information, the guidance document offers advice on how MSAs can develop a robust rationale for injury scenarios and probability estimations. It also includes examples of checklists that can help with interpreting test reports and guiding MSAs through RAs on products that they have less experience with.

The approach used for developing the guidance document is summarised in the figure below.

1

Preparation of the draft structure and collection of MSA cases

- The technical expert prepared the draft structure of the guidance document based on the discussion with the MSAs during the KoM
- Difficult cases experienced by the MSAs were collected

2

Validation of the structure

- The MSAs commented on and validated the proposed structure of the guidance document

3

Discussion on difficult cases

- During project meetings, the MSAs and the technical experts discussed the selected cases
- Based on the discussions, the technical expert was able to fine-tune the guidance to focus on areas where MSAs need further guidance

4

Preparation of draft guidance

- Based on the feedback received from the MSAs, the technical expert prepared the draft guidance document

5

Fine-tuning based on MSA feedback

- The MSAs reviewed and commented on the document (which was further fine-tuned as a result)

2.2.2 Development of the risk management guidance document

The guidance document on risk management was developed to support MSAs in the management of identified risks. The purpose of this document is to:

- provide guidance on risk management;
- discuss risk management challenges and offer tools and strategies to overcome them.

Based on the exchange with MSAs, the second guidance document discusses appropriate and effective risk management actions to mitigate and eliminate consumers' exposure to identified risks. In addition to providing indicative lists of corrective actions, the document also includes guidance on how MSAs can overcome common risk management challenges, such as deciding on the appropriate corrective action for low to medium risks. Finally, the document includes useful advice on how to cooperate with EOs and online marketplaces on risk management.

The approach used for developing the guidance document is summarised in the figure below.

1 Preparation of the draft structure and collection of MSA cases

- The technical expert prepared the draft structure of the guidance document on risk management
- Specific risk management challenges were collected via a survey and individual interviews with MSAs

2 Validation of the structure

- The MSAs commented on and validated the proposed structure of the guidance document

3 Discussion on difficult cases

- During project meetings, the MSAs and the technical experts discussed specific risk management challenges
- Based on the discussions, the technical expert was able to fine-tune the guidance to focus on areas where MSAs need further guidance

4 Preparation of draft guidance

- Based on the feedback received from the MSAs, the technical expert prepared the draft guidance document

5 Fine-tuning based on MSA feedback

- The MSAs reviewed and commented on the document (which was further fine-tuned as a result)

3. Conclusions and recommendations

3.1 General conclusions

The RAM HA provided an important forum for the participating MSAs to discuss challenges and best practices related to risk assessment and risk management. The discussions helped identify the areas in which MSAs need more guidance. Based on the case-solving workshops and feedback from the MSAs, the technical expert produced two guidance documents. Focusing on risk assessment and risk management, the guidance documents include injury scenarios and risk probabilities for each of the case studies discussed during the activity and provide tools and strategies for performing robust RAs and developing appropriate and effective risk management actions. The combination of guidance and real-life case studies allowed MSAs to apply the newly acquired concepts and tools in practice to help with the assessment and management of similar risks in the future.

3.2 Lessons learned

- **Online project communication and MSA engagement.** The Contractor used the Wiki platform as a project communication tool, which enabled all participating MSAs to quickly find and approve project documents and exchange views and knowledge during the activity. The Wiki platform is a suitable tool for facilitating online cooperation and MSA engagement and should be used even more actively by all parties to ensure that MSAs are informed and engaged in-between meetings.
- **Disseminating and referencing key past guidelines and tools.** In order to make sure that all participants have similar levels of knowledge on RA and risk management topics, and are familiar with key documents and tools from previous projects, it is important to share and reference these materials before and during meetings. While the content and outputs of the activity should not replicate those of previous years, existing materials can complement the discussions, tools and strategies being developed in the ongoing activity.
- **Providing practical tools and strategies on risk assessment and risk management**. In addition to the discussions and exchanges of views, guidance on specific challenges is particularly important to MSAs. Providing practical tools and strategies on how to overcome challenges related to RA and risk management, and demonstrating the application of these solutions in both the case-solving workshops and the guidance document, has proven to be of added value for MSAs.

3.3 Recommendations

Based on the discussions during the meetings of the activity, a number of recommendations were formulated.

For consumers

Check Safety Gate before purchasing a product. If consumers are unsure whether a product may pose a risk, they should check Safety Gate to see if any EU/EEA MSAs have submitted a notification regarding the product in question.

Check for information about unsafe or defective products on MSA websites. Some MSAs have created dedicated product safety websites that inform consumers about unsafe and defective products[4]. Consumers should regularly consult these websites and follow the instructions and guidance provided on how to return or dispose of unsafe or defective products.

For EOs

Be aware of your obligations under the applicable legislation. When placing products on the market, economic operators need to ensure that they are designed and manufactured in accordance with applicable legal requirements.

Use the RAG tool to assess risks associated with your products. EOs should use the RAG tool to assess the risks of products marketed and/or manufactured by them in order to ensure that only safe products are marketed to consumers.

Cooperate with MSAs on RAs and risk management. EOs are legally obliged to notify MSAs when they become aware of a product safety issue. EOs and authorities should maintain an open dialogue and actively cooperate in the RA and risk management process.

Have a corrective action plan in place to mitigate and eliminate the risks posed by products in the supply chain or on the market. Make sure you have the documents and structures for this process already in place, so that decisions can be made relatively quickly, and action can be taken in a timely manner. Monitoring the corrective action to determine its effectiveness in managing and reducing the risk is an essential part of the plan and can provide useful lessons for future actions.

For national authorities

Continue the exchange of views and best practices on difficult risk assessment and risk management cases to further increase consistency across authorities. During the activity, MSAs discussed various cases related to RA and risk management. This exchange of views helped authorities to find common solutions to challenges, and ultimately increase the consistency of RA and risk management in the EU/EEA.

Disseminate the CASP 2021 results. MSAs are encouraged to further disseminate the results and deliverables of the CASP 2021 project.

Identify issues related to emerging risks associated with novel products[5]. Issues should be raised to the RAPEX/CSN networks and EC when needed in order to foster knowledge-sharing and develop further guidance.

[4] See for instance https://produkter.dk/ or https://www.farligeprodukter.no/.

[5] Novel products refer to newly developed or improved products that are first introduced to the market and often rely on new technologies that may pose new risks.

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.

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.

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.

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

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

Horizontal activities (HAs)

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

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

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

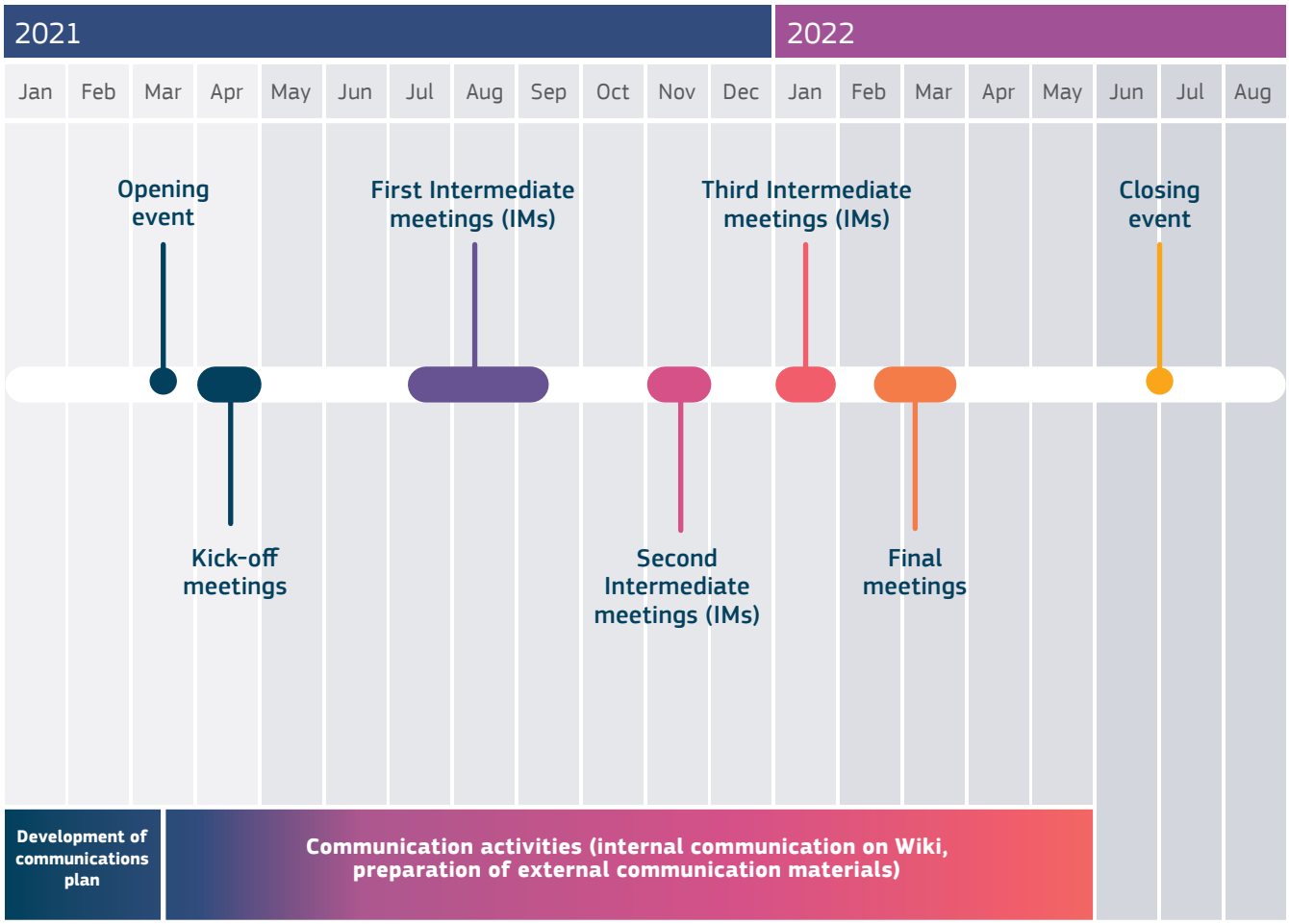
Contractor EY/Pracsis
- Coordinates the implementation and organisation of the activities
- Provides technical & logistical background
- Responsible for reporting, communication and the dissemination of the outcomes

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 HA)
- 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. HA work plan



INCEPTION	FIELDWORK	REPORTING	EXTERNAL COMMS
Desk research	Further research on topics defined during the kick-off meetings	Final meetings – presenting final outcomes	Launch of the communications campaign
Drawing initial conclusions	Final validation of activities' approaches	Validation and discussion of lessons learned	
Finetuning objectives	Conducting intermediate meetings, integrating inputs	Drafting of final reports	
Kick-off meetings – refining approaches	Finalisation of work/guidance documents and production of knowledge sharing tools	Dissemination	Assessing the impact

3. Overview of the HA approach

0

Pre-CASP process

- DG JUST conducted a priority-setting exercise to select the topics of common interest to market surveillance authorities (MSAs).
- The CASP 2021 horizontal activities were selected through a consultation organised by DG JUST and reflect current interest in online market surveillance, risk assessment methodologies and crisis management.

1

Data collection and analysis

- Using various tools, such as surveys, interviews and desk research, the contractor collected the necessary background information.
- The outcomes were analysed to identify needs, gaps and challenges.
- The project's objectives and work plan were further finetuned and shared on the internal Wiki platform alongside the findings of the initial research.

2

Kick-off meetings

- Participating market surveillance authorities discussed the goals and deliverables during the kick-off meeting of each horizontal activity.
- Based on the desk research and data collection results, the approach was further refined.
- Following the meeting, work documents were shared on the Wiki platform where MSAs had the possibility to exchange views.

3

IMs

- During two intermediate meetings, the progress in each activity was presented and MSAs advanced on the various guidance documents with the help of the relevant field expert.
- Because of the complexity of the topic, a third intermediate meeting was held for the online market surveillance activity.

4

Conclusions, recommendations and reporting

- During the final meetings, the MSAs validated the final version of the relevant documents, and discussed lessons learned and possible insights in each horizontal activity.
- Work/guidance documents and other knowledge-sharing tools are provided to all authorities to help put the learnings into practice.

5

External communications

The external communication activities were launched at the closing event, marking the start of a 2–3-week long pan-European information campaign.

Tools

Final reports are produced for each horizontal activity and for the CASP 2021 project as a whole. They are available in all official EU languages plus Norwegian and Icelandic and have been disseminated to all market surveillance authorities.

Audio-visual clips summarising the outcomes of the CASP 2021 project were produced.

Channels

The communication material is disseminated through:

- *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
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