EN

European Commission

CASP2022

Coordinated Activities on the Safety of Products

Hygiene products 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
GPSD	General Product Safety Directive (2001/95/EC)
ISO	International Organization for Standardization
MSA	Market surveillance authority
PSA	Product-specific activity
RAG tool	Risk Assessment Guidelines tool
RAPEX Guidelines	Decision (EU) 2019/417
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SVHC	Substances of very high concern

Executive summary

Objectives of the activity

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

Product scope

1. Baby diapers
2. Non-medical incontinence pads, liners or guards
3. External menstrual products (sanitary pads and pantyliners)
4. Internal menstrual products (tampons with or without an applicator)

Testing criteria

The testing plan included the following European Standards (ENs) and Regulation:

- EN ISO 10993-18 – Chemical characterisation of materials (AET calculation)
- EN ISO 10993-5 – Tests for in vitro cytotoxicity
- EN ISO 10993-23 – Tests for irritation
- EN ISO 11737 – Bioburden testing – determination of a population of microorganisms (tampons only)
- REACH – Screening for substances of very high concern (SVHC).

Results

In total, 30 hygiene products were tested for this activity, including:

- 11 diapers
- two non-medical incontinence products;
- 11 external menstrual products
- six internal menstrual products.

A total of 73% of the samples (22) met all the requirements of the testing plan. Eight samples did not meet the requirements of the test for cytotoxicity (cell-growth inhibition <30%).

All samples met the requirements according to the MSAs' checks on the warnings, markings and instructions.

Key recommendations

For consumers

- Follow the instructions of use and pay attention to the recommended time of use.
- Check the integrity of the product before using it.
- Change diapers regularly or as soon as they become soiled.
- Change hygiene products regularly.
- Pay attention to irritation or a rash on the skin area in contact with the product.

For economic operators

- Consider biocompatibility when choosing raw materials and production processes for hygiene products.
- Raise consumer awareness on the proper use of hygiene products.

For public authorities

- Keep monitoring the market for hygiene products.
- Further investigate the effects of cytotoxicity in hygiene products.
- Evaluate the option of regulating hygiene products at EU level.

For standardisation organisations

- Evaluate different options for the standardisation of the safety of hygiene products, including baby diapers.

Conclusions

In the absence of sector specific legislation for hygiene products, the testing plan for this activity was designed to ensure relevant, accurate, reliable, and comparable tests according to biological safety standards related to medical devices as well as selected substance testing according to REACH across a range of hygiene products.

All hygiene products met the requirements of the selected substance testing according to REACH and most of them met the requirements of the harmonised standards on the biological and chemical evaluation of medical devices.

The results show that, apart from one sanitary pad, it was predominantly baby diapers (seven out of 11 samples) that did not meet the requirements of EN ISO 10993-5: 2009 – Tests for in vitro cytotoxicity.

The MSAs have assessed the safety risk in relation to cytotoxicity as low. Given the limited data available, it remains important to further monitor and test hygiene products to ensure they are safe.

As babies belong to a particularly vulnerable group it is important that manufacturers assess the safety of the materials used in the production process, and that parents and caregivers follow the instructions and recommended time of use for diapers.

1. Overview of the activity

1.1. Participating MSAs

Four MSAs from four EU Member States participated in the product-specific activity (PSA) on hygiene products.

Table 1 - **List of participating MSAs**

COUNTRY	MSA
Austria	Federal Ministry of Social Affairs, Health, Care and Consumer Protection (BMSGPK)
Belgium	Federal Public Service Public Health, Food Chain Safety and Environment
Croatia	State Inspectorate
France	General Directorate for Competition Policy, Consumer Affairs and Fraud Control

1.2. Product scope and testing criteria

1.2.1. Product scope

The MSAs agreed to restrict the product scope to disposable hygiene products that are not classified as medical devices and therefore not regulated by the Medical Devices Regulation (EU) 2017/745[1]. Baby diapers, non-medical incontinence pads as well as external and internal menstrual products were defined as the four main groups for this activity.

BABY DIAPERS

NON-MEDICAL INCONTINENCE PADS

EXTERNAL MENSTRUAL PRODUCTS

INTERNAL MENSTRUAL PRODUCTS

[1] EUR-Lex - 32017R0745 - EN - EUR-Lex (europa.eu)

1.2.2. Testing criteria

According to the General Product Safety Directive (2001/95/EC) (GPSD)[2,3] all products placed on the Single Market must be safe. While hygiene products are not regulated by product specific legislation, the GPSD states that, in the absence of specific regulations and when ENs established under mandates set by the European Commission (EC) are not available, the safety of products should be assessed using national standards; and transposing any other relevant European or international standards, Commission recommendations, codes of good practice, the state of the art, and the levels of safety that consumers may reasonably expect. Following this approach, the testing plan was composed of relevant EN standards applied by analogy and of the provisions for articles in the REACH Regulation[4] on substances of very high concern (SVHC), which are applicable to hygiene products. These tests were selected by the technical expert and approved by the participating MSAs. The complete testing plan is listed in *Table 2*.

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 for the MSAs.

Table 2 - **Testing plan**

STANDARD/LEGISLATION	TESTS
EN ISO 10993-5: 2009 Biological evaluation of medical devices	Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-18 Biological evaluation of medical devices	Part 18: Chemical characterisation of medical device materials within a risk management process
EN ISO 10993-23: 2021 Biological evaluation of medical devices	Part 23: Tests for irritation
ISO 11737-1:2018 + Amd. 1: 2021	Sterilisation of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products (tampons only)
REACH	SVHC screening – Solvent extraction by GC-MS or HPLC (or other analytical methods). Testing was performed on finished products (product as a whole).

2. Sampling and testing

2.1. Sampling distribution and sampling channels

Each MSA was invited to sample a total of seven products. The MSAs agreed to sample products from each of the four product categories, taking into account the availability of the products on the national markets.

A total number of 30 samples were collected by the MSAs and sent to the laboratory for testing. The samples included 11 baby diapers, 2 non-medical incontinence pads, 11 external menstrual products (sanitary pads and pantyliners) and 6 internal menstrual products (tampons with/without an applicator). All 30 samples were collected from physical shops.

Table 3 - **Number of samples collected by participating MSAs**

COUNTRY	MSA	BABY DIAPERS	NON-MEDICAL INCONTINENCE PRODUCTS	EXTERNAL MENSTRUAL PRODUCTS	INTERNAL MENSTRUAL PRODUCTS
Austria	Federal Ministry of Social Affairs, Health, Care and Consumer Protection	3	0	2	2
Belgium	Federal Public Service Public Health, Food Chain Safety and Environment	4	0	2	1
Croatia	State Inspectorate	3	0	5	1
France	General Directorate for Competition Policy, Consumer Affairs and Fraud Control	1	2	2	2
	TOTAL	11	2	11	6

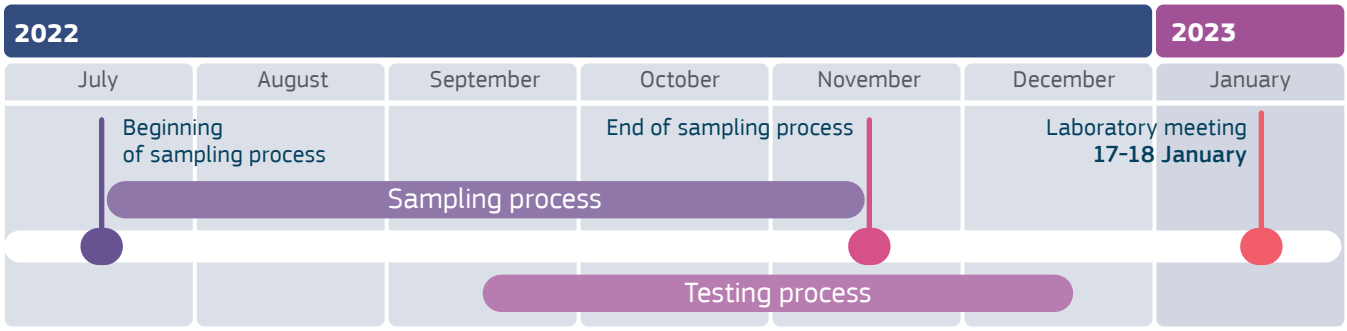
[2] EUR-Lex - 32001L0095 - EN - EUR-Lex (europa.eu)
[3] The Regulation (EU) 2023/988 on general product safety has been published in the Official Journal on 23 May 2023: EUR-Lex - 32023R0988 - EN - EUR-Lex (europa.eu). It enters into force on 12 June 2023 and into application on 13 December 2024.
[4] EUR-Lex - 32006R1907 - EN - EUR-Lex (europa.eu)

2.2. Testing process

The testing laboratory for this activity was selected through a tender procedure, launched in June 2022. The tender specifications were sent to 57 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 the experts and test reports. Four laboratories submitted an offer within the given timeframe. Based on the completeness and competitiveness of the offers, three laboratories were pre-selected and invited to an interview to further discuss their offers. 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. Due to the technical complexity, the project team invited representatives from the three pre-selected laboratories to present their offers and answer questions from the MSAs during the meeting.
The MSAs selected the laboratory that was awarded the highest number of final points based on the quality and financial competitiveness of their offer.

Following the selection of the laboratory, the MSAs were given two months to collect the samples and send them to the laboratory. The sampling process was extended to allow MSAs to sample additional products. The testing process encountered no delays and was completed on 21 December 2022. The laboratory meeting took place on 17–18 January 2023.

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



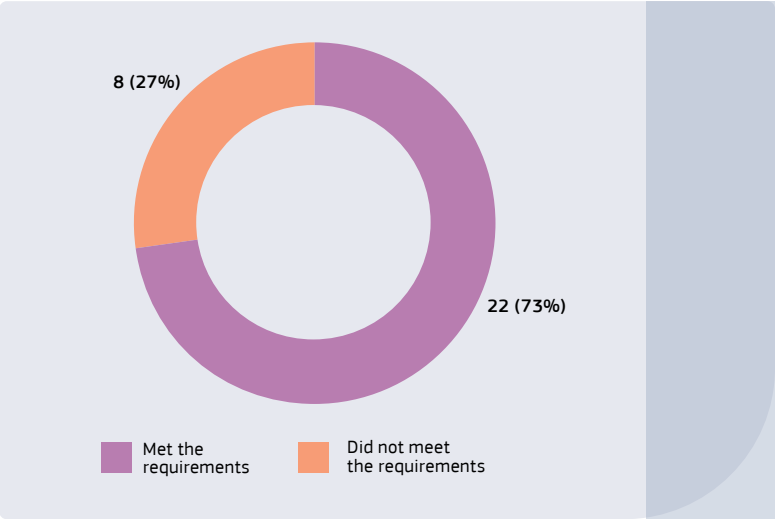
3. Test results

3.1. Overview of the test results and main findings

A total of 22 out of the 30 samples tested by the laboratory met all the requirements outlined in the final testing plan, as shown in the chart below. The remaining eight samples did not meet the requirements of EN ISO 10993-5: 2009 – Tests for in vitro cytotoxicity.

The MSAs performed checks on warnings, markings and instructions in their national language(s) and all 30 samples met the requirements.

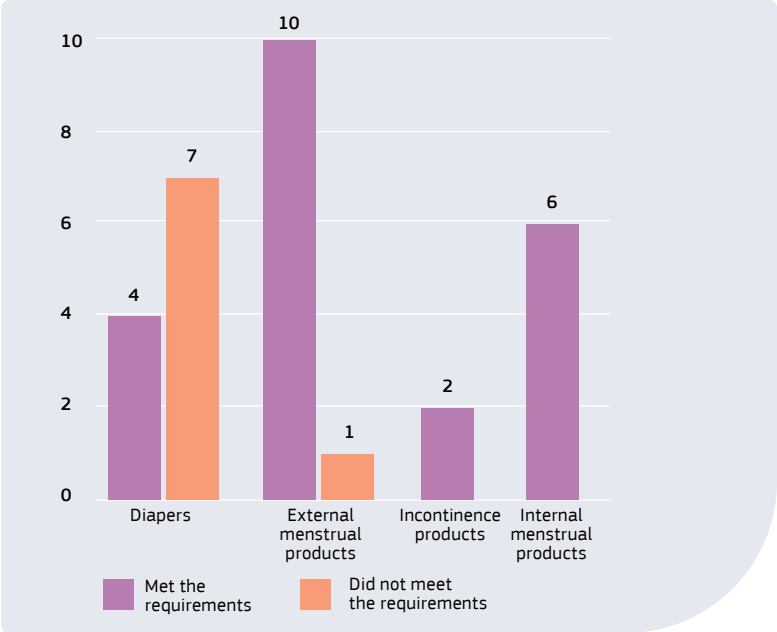
Figure 2 - **Overall test results (N=30)**



3.2. Results per product type

While all the incontinence products and internal menstrual products tested met the requirements, seven diapers and one sanitary pad did not meet the requirements of EN ISO 10993-5: 2009 – Tests for in vitro cytotoxicity.

In order to further investigate the reason of the cytotoxicity failure, the laboratory took the initiative of selecting one diaper that initially did not meet the requirements of the cytotoxicity test and re-tested it without the superabsorbent material. Under these conditions, the product passed the test. This corroborates the assumption of the laboratory that it might be the superabsorbent material that is responsible for the high percentage of the cell growth inhibition.



3.3. Conclusions on the test results

All hygiene products met the requirements of the selected substance testing according to REACH and most of them met the requirements of the harmonised standards on the biological and chemical evaluation of medical devices that were applied by analogy. No SVHC above the limit values were detected in any of the products, and all internal menstrual products met the requirements of the bioburden test (ISO 11737-1: 2018 + Amd. 1: 2021). Only one sanitary pad out of 11 external menstrual products did not meet the requirements of EN ISO 10993-5: 2009 – Tests for in vitro cytotoxicity. Out of the 11 commercial brands of baby diapers tested, four met all the requirements.
In seven diapers a cytotoxic effect was observed in L292 cells (cell growth inhibition ≈95%).

Cytotoxicity in these materials points to the presence of chemical substances that can potentially damage human keratinocytes and cause skin barrier disruptions. While the detected cytotoxicity can therefore be considered a risk factor in terms of irritation and other infections when the skin comes into contact with the chemical substances, a further investigation by a toxicologist is required to identify the detected substances and perform a risk assessment based on the appropriate toxicological data. In addition to the chemical evaluation, the diaper absorption and retention capacity are also important to take into account when assessing the risk of cytotoxic fluid migrating from inner layers to outer parts that are in contact with the skin.

All products met the requirements of the checks on warnings, markings and instructions (which assess the completeness of the information and warnings on the correct use of hygiene products in the national language(s) of the country).

4. Risk assessment and measures

4.1. Risk assessment results

According to the GPSD, all products placed on the EU market must be safe. In the absence of specific legislation for hygiene products and when the ENs established under mandates set by the Commission are not available, the GPSD states that the safety of products should be assessed using any other relevant national, European or international standards, codes of good practice, the state of the art and the levels of safety that consumers may reasonably expect.

When assessing whether a product poses a risk, the approach must be based on Decision (EU) 2019/417 (the RAPEX Guidelines)[5]. To develop the risk assessments, the MSAs used the Risk Assessment Guidelines (RAG)[6] tool managed by the EC.

The MSAs assessed the eight samples that did not meet the requirements as posing a low risk given the lack of biocompatibility data and the uncertainty regarding the cause and impact of the detected cytotoxicity. In the MSAs' opinion, cytotoxicity values should be evaluated in relation to other biocompatibility data and the intended use of the product.

4.2. Measures adopted by the MSAs

Based on the test results and the risk assessments performed, the MSAs decide which measures have to be taken regarding the products that did not meet the requirements of the testing standards and regulations applied. Considering that the risk posed by the eight products that did not meet the requirements of the in vitro cytotoxicity test was considered low, the MSAs informed the economic operators about the results and did not adopt any measures.

[5] Commission Implementing Decision (EU) 2019/417 of 8 November... – EUR-Lex (europa.eu)
[6] RAG ECL V10 (europa.eu)

5. Conclusions and recommendations

5.1. Conclusions

In the absence of sector specific legislation for hygiene products, the testing plan for this activity was designed to ensure relevant, accurate, reliable, and comparable tests according to biological safety standards related to medical devices (EN ISO 10993 series) as well as selected substance testing (REACH) across a range of hygiene products.

All hygiene products met the requirements of the selected substance testing according to REACH and most of them met the requirements of the harmonised standards on the biological and chemical evaluation of medical devices. No SVHC above the limit values were detected in any of the products, and all internal menstrual products met the requirements of the bioburden test.

The results show that, apart from one sanitary pad, it was predominantly baby diapers (seven out of 11) that did not meet the requirements of EN ISO 10993-5: 2009 – Tests for in vitro cytotoxicity.

The MSAs have assessed the safety risk in relation to cytotoxicity as low. Given the limited data available, it remains important to further monitor and test hygiene products to ensure they are safe.

As babies belong to a particularly vulnerable group it is important that manufacturers assess the safety of the materials used in the production process and that parents and caregivers follow the instructions and recommended times of use for diapers.

5.2. Recommendations for stakeholders

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

For consumers

- Follow the instructions of use and pay attention to the recommended time of use.
- Check the integrity of the product before using it.
- Change diapers regularly or as soon as they become soiled.
- Change hygiene products regularly.
- Pay attention to irritation or rash on the skin area in contact with the product.

For European and national authorities

- Keep monitoring the market for hygiene products.
- Further investigate the effects of cytotoxicity in hygiene products.
- Evaluate the option of regulating hygiene products at EU level.

For economic operators

- Consider biocompatibility when choosing the raw materials and production processes for hygiene products.
- Raise consumer awareness on the proper use of hygiene products.

For standardisation organisations

- Evaluate different options for the standardisation of the safety of hygiene products, including baby diapers.

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

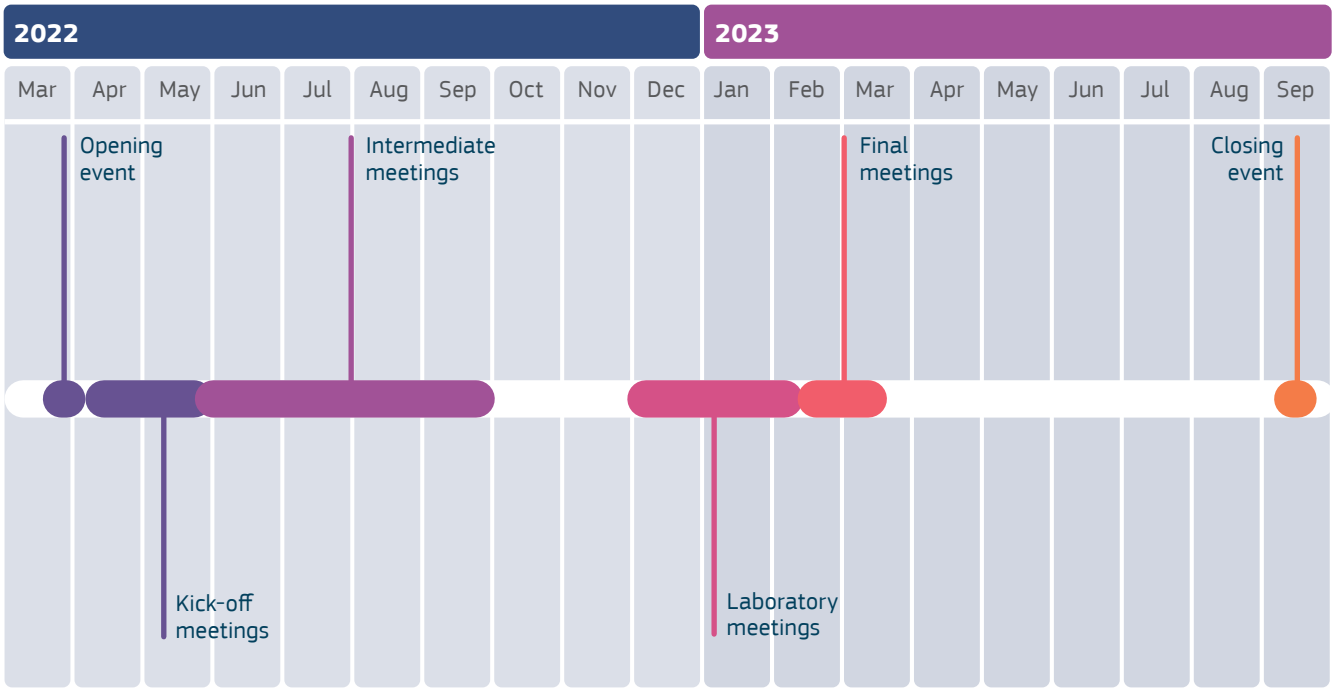
Contractor EY/Pracsis
- Coordinates the implementation and organisation of the activities
- Provides technical & logistical background
- Responsible for reporting, communication and the dissemination of the outcomes

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
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