



European
Commission



CASP2022

Coordinated Activities
on the Safety of Products



Chemicals
in toys



Final
Report

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List of abbreviations

ABBREVIATION	DESCRIPTION
BPA	Bisphenol A
CASP	Coordinated Activities on the Safety of Products
DG JUST	Directorate-General for Justice and Consumers of the European Commission
EEA	European Economic Area
EC	European Commission
EU	European Union
MSA	Market surveillance authority
PAHs	Polycyclic-aromatic hydrocarbons
PSA	Product-specific activity
PVC	Polyvinyl chloride
RAG	Risk Assessment Guidelines
The RAPEX Guidelines	Commission implementing decision (EU) 2019/417 laying down guidelines for the management of the European Union Rapid Information System
REACH	Regulation (EC) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
TSD	Directive 2009/48/EC on the safety of toys

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) and European Economic Area (EEA) countries to jointly ensure that unsafe products are swiftly removed from the Single Market. This activity focused on identifying dangerous levels of certain chemicals in toys. The products were sampled both online and from physical shops, and tested following commonly agreed criteria in a European laboratory selected by the participating MSAs.

Product scope

The activity covered **soft and hard plastic toys** intended for children **above and under 36 months of age**.

Testing criteria

Testing focused on detecting the presence of unauthorised dangerous chemicals that pose risks to human health. More specifically, the testing plan focused on the detection of:

- phthalates, polycyclic-aromatic hydrocarbons (PAHs) and cadmium, according to Annex XVII of Regulation (EC) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH);
- the migration of 17 metals restricted by the Toy Safety Directive (TSD) with the exception of chromium (VI) and organic tin;
- formaldehyde, bisphenol A (BPA), phenol and flame retardants, in relation to Appendix C to Annex II of the TSD.

Results

- Out of the 94 toys tested, 8 did not meet at least one of the health and safety requirements looked at. Dangerous non-authorised chemicals (phthalates and BPA) were detected exclusively in toys entirely or partially made of soft plastic.
- Overall, 14% of the toys intended for children above 36 months of age did not meet the requirements, against 4% for toys intended for children under 36 months.
- Examinations of the labelling – warnings, markings and instructions – performed by the MSAs showed that 33 out of 94 samples did not meet the requirements.

Key recommendations

For consumers

- Only purchase toys from trustworthy retail channels.
- Check that the toys bear the CE mark.
- Monitor younger children (under the age of 36 months) when they are playing with toys of older siblings that might be put in the mouth.
- Be careful not to buy low-quality soft plastic toys, they may pose a higher chemical risk.

For economic operators

- Be aware of your obligations under the applicable legislation.
- Pay particular attention to toys made of soft plastic.
- Know your supplier. Make a careful assessment when choosing who you work with.

For public authorities

- Focus market surveillance efforts on soft plastic toys: soft plastic toy materials such as soft polyvinyl chloride (PVC) may contain the most problematic chemicals.
- Keep focusing on chemicals in toys. Chemical risks are one of the most significant risks recorded in Safety Gate.

Conclusions

The testing campaign detected phthalates and BPA in eight of the tested samples. Although only 9% of the tested samples did not meet the requirements, the chemical risks related to the presence of phthalates and BPA in quantities above the limit values are serious.

The dangerous chemicals were exclusively found in soft plastic toy materials, highlighting the fact that soft plastic remains one of the materials that presents the most risks.

MSAs issued two Safety Gate notifications based on the outcome of this PSA (three notifications are still pending) and asked the economic operators to withdraw the products from the market or recall them from the consumers when dangerous chemicals exceeding limit values were detected.

1. Overview of the activity

1.1. Participating MSAs

Nine MSAs from nine EU Member States participated in the Chemicals in toys product-specific activity (PSA).

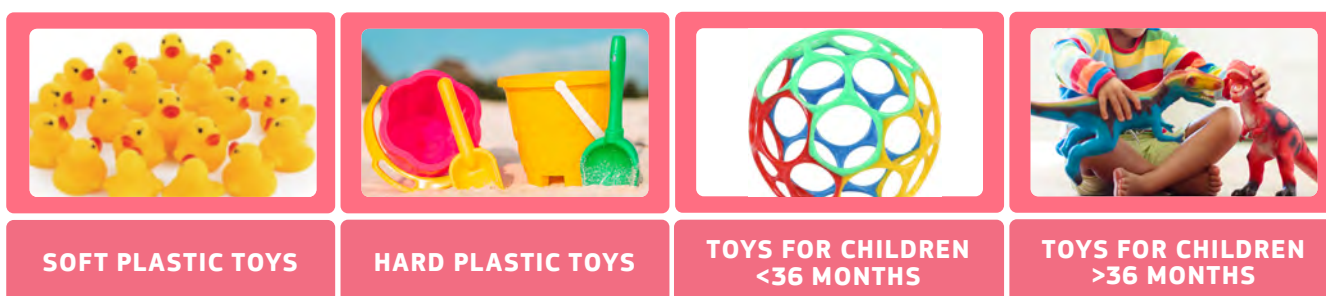
Table 1 - List of participating MSAs

COUNTRY	MSA
Austria	Federal Ministry of Social Affairs, Health, Care and Consumer Protection
Estonia	Consumer Protection and Technical Regulatory Authority
France	General Directorate for Competition Policy, Consumer Affairs and Fraud Control
Ireland	Competition and Consumer Protection Commission
Malta	Malta Competition and Consumer Affairs Authority
Poland	Office of Competition and Consumer Protection
Slovak Republic	Slovak Trade Inspection
Slovenia	Health Inspectorate
Sweden	Swedish Chemicals Agency

1.2. Product scope and testing criteria

1.2.1. Product scope

The MSAs agreed to restrict the product scope to soft and hard plastic toys intended for children of all ages (above and under 36 months of age).



1.2.2. Testing criteria

Based on discussions with the MSAs and the technical expert, it was agreed to test 37 different hazardous chemicals often found in toy products:

- four phthalates banned in all toy polymer materials due to serious risk (irrespective of age or ability to mouth) – Entry 51 of REACH¹, Annex XVII;
- three phthalates banned in toy polymer materials that children can place in their mouths – Entry 52 of REACH, Annex XVII;
- eight PAHs in soft/dark elastomer/rubber materials, which can be in contact with the oral cavity or where there is prolonged or short-term repetitive skin contact under reasonably foreseeable conditions – Entry 50 of REACH, Annex XVII;
- cadmium – Entry 23 of REACH, Annex XVII;
- all 17 metals with migration limits restricted by the TSD²;

- formaldehyde, BPA, flame retardants (TCEP, TCPP, TDCP)³ and phenol, restricted by Appendix C to Annex II of the TSD.

Such chemicals are restricted either in their content by weight or by migration limits from the toy when chewed or sucked by a child. These restrictions have been determined at EU level over time and are based on scientific safety data and 'state of the art' knowledge.

The toxicity of these unsafe chemicals varies. They are often found in the toy product, either as a result of processing or because they have been purposefully added to perform a specific function, such as improving the flexibility of the toy or acting as flame retardant or preservative.

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

¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R1907&from=EN>

² <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009L0048&from=EN>

³ CPP = tris(2-chloro-1-methylethyl) phosphate; TDCP = tris[2-chloro-1-(chloromethyl)ethyl] phosphate; and TCEP = tris(2-chloroethyl) phosphate

2. Sampling and testing

2.1. Sampling distribution and sampling channels

The sampling was carried out on the basis of a pre-selection by each of the MSAs, in line with the peculiarities of each market.

The participating MSAs collected 95 samples in total. However, one sample (diving ring) was eventually assessed as a non-toy considering that its main purpose is educational (learning how to dive)⁴.

The majority of the sampled toys were made of either soft or hard plastic. Four samples contained both soft and hard plastic components. Sampling was performed both online and in physical shops.

Table 2 - Number of samples collected by participating MSAs

COUNTRY	MSA	TOTAL NUMBER OF SAMPLES
Austria	Federal Ministry of Social Affairs, Health, Care and Consumer Protection	10
Estonia	Consumer Protection and Technical Regulatory Authority	10
France	General Directorate for Competition Policy, Consumer Affairs and Fraud Control	14
Ireland	Competition and Consumer Protection Commission	10
Malta	Malta Competition and Consumer Affairs Authority	11
Poland	Office of Competition and Consumer Protection	10
Slovak Republic	Slovak Trade Inspection	10
Slovenia	Health Inspectorate	10
Sweden	Swedish Chemicals Agency	9
TOTAL		94

Table 3 - Type of samples collected and sampling channels

MATERIAL			AGE CATEGORY		SAMPLING CHANNEL	
Soft plastic	Hard plastic	Mixed	Under 36 months	Above 36 months	Online	Physical shop
44	46	4	50	44	19	75

2.2. Testing process

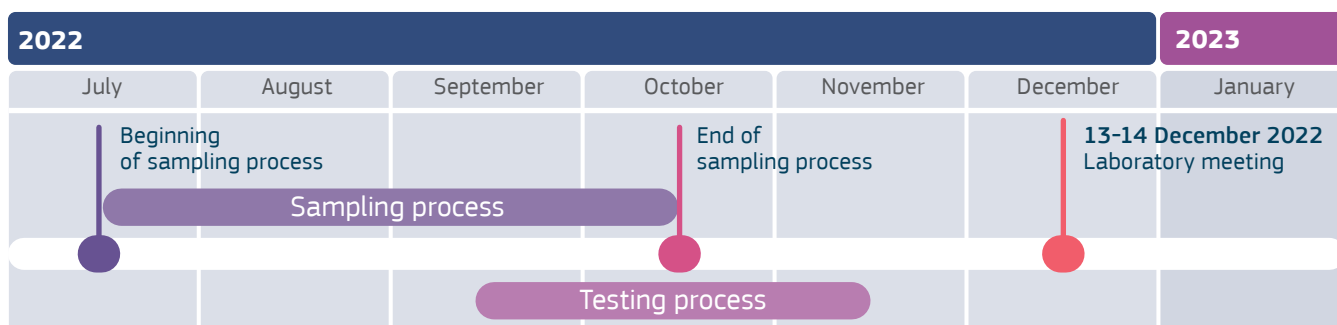
The testing laboratory for this activity was selected through a tender procedure, launched in May 2022. The tender specifications were sent to 107 laboratories in the EU/EEA that had been identified following the project team's laboratory engagement strategy. Each laboratory was asked to submit an offer 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 report templates. Overall, 14 laboratories submitted an offer within the given timeframe. Based on the completeness and competitiveness of the offer, five laboratories were pre-selected and invited to an interview to further discuss their offer. During the intermediate meeting the MSAs were

presented with comparative analyses of the technical quality and financial aspects of the offers received from the laboratories.

The MSAs selected the laboratory that was awarded the highest number of 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 19 November 2022. The laboratory meeting took place on 13–14 December 2022.

Figure 1 - Timeline of the sampling and testing process



⁴ The product was considered out of scope and the results of the testing are not included in the figures of this report.

3. Test results

3.1. Overview of the test results and main findings

Overall, eight out of the 94 samples tested did not meet at least one of the requirements outlined in the testing plan.

The majority of samples (80%) came from physical shops. There were no major differences in the test results based on the retail channel: 10% of the samples collected online and 8% of the samples collected from physical shops did not meet the requirements of the testing plan.

The MSAs performed checks on warnings, markings and instructions in their national language(s). In total, 33 out of 94 samples did not meet the requirements. The most common non-compliance issues detected were missing CE marks or CE marks that were an incorrect size and shape, missing information regarding a single point of contact and incorrect age warnings.

If we consider both the chemical tests performed by the laboratory and the warnings, markings and instruction checks performed by the MSAs, a total of 35 samples did not meet at least one of the requirements.

Figure 2 - Overall test results (chemical testing) (N=94)

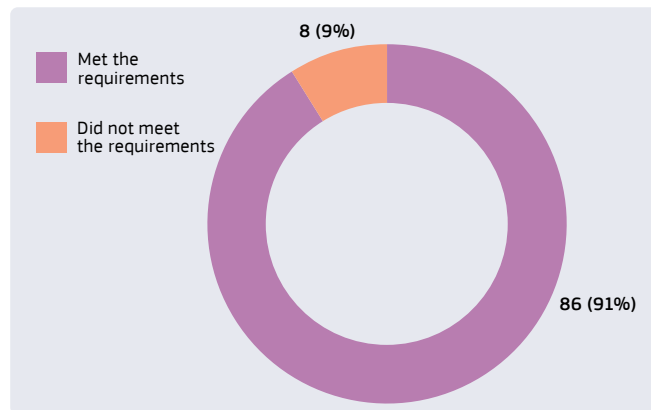
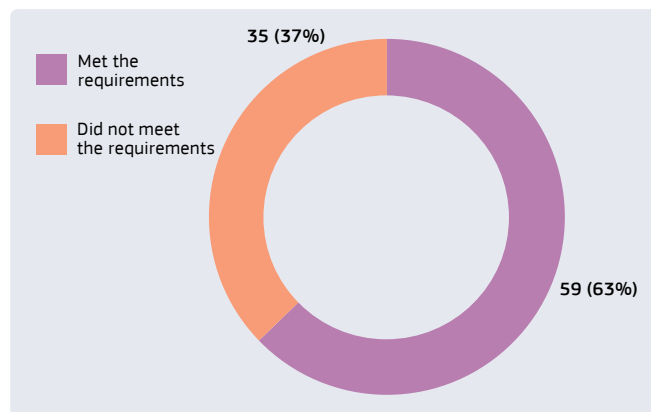


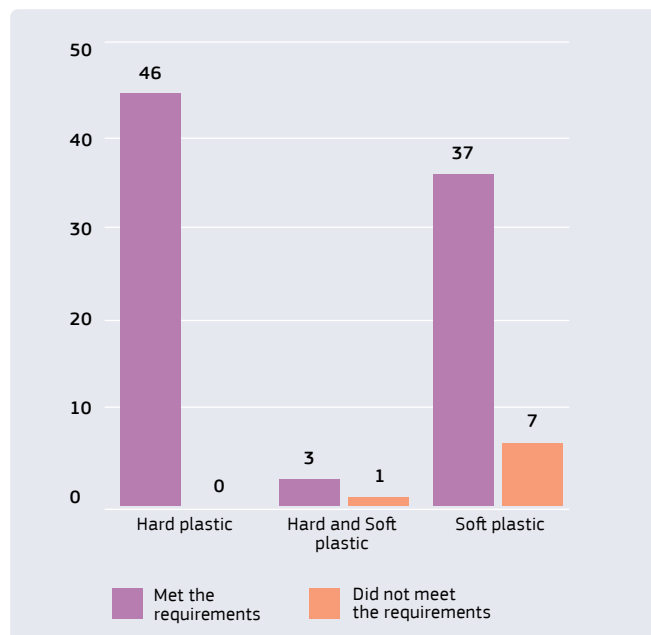
Figure 3 - Overall test results (including warnings, markings and instructions) (N=94)



3.2. Results per type of material

The participating MSAs collected 46 toys made of hard plastic, 44 made of soft plastic, and four containing both soft and hard plastic components. While all the hard plastic toys passed the chemical tests, limit values for phthalates or BPA were exceeded in eight samples made completely of soft plastic or made of both materials (see Figure 4).

Figure 4 - Test results per type of material (N=94)

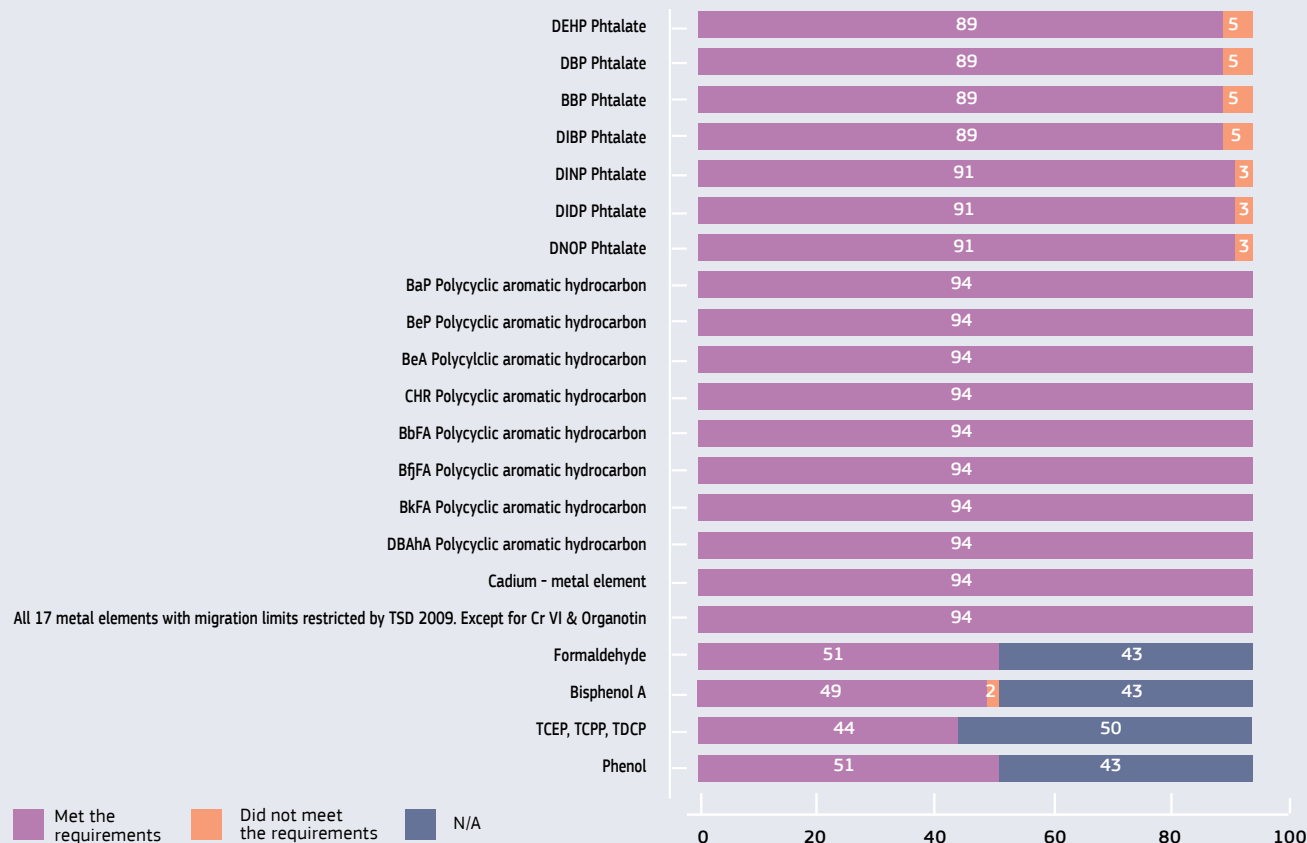


3.3. Results per chemical substance

The eight samples that did not respect the legal limit values showed exceeding values for BPA and seven different types of phthalates (see Figure 5).

Phthalates that exceeded limit values were especially detected on dolls' faces and legs made of pink soft plastic, while BPA that exceeded limit values was detected in two duck bath toys.

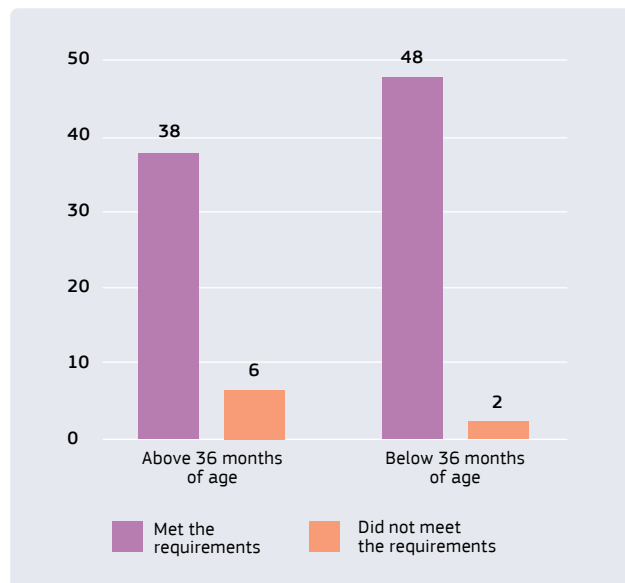
Figure 5 - Test results per chemical substance (N=94)



3.4. Results per age category

Overall, 44 out of the 94 tested toys were intended for children above 36 months and 50 for children under 36 months. Toys for children above 36 months presented a higher failure rate (14%) than toys for children under 36 months (4%).

Figure 6 - Overall test results – toys intended for children above and below 36 months (chemical testing) (N=94)



3.5. Conclusions on the test results

Chemical risks

The activity showed that 91% of the sampled toys met the chemical requirements set down in the testing plan.

Chemical substances that exceeded the limit values were found exclusively in toys either entirely or partially made of soft plastic.

The **prohibited phthalates** were discovered in **six different samples**. This finding was not surprising as phthalates are in many cases purposefully used by producers to increase the flexibility, transparency and durability of plastic. The phthalates tested in this activity affect reproductive functions and interfere with the human hormonal system (endocrine disruptors).

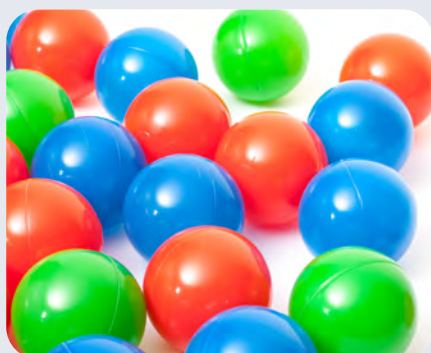
In addition to the detection of phthalates, **the only other unauthorised dangerous chemical** discovered was **BPA** (found in two bath ducks out of 51 samples tested for this substance).

This was a surprising result for the participating MSAs.

BPA is a chemical used to strengthen plastics and to increase their durability. It is an endocrine disruptor, therefore, a substance capable of damaging health by altering the endocrine balance, especially in early childhood. It is classified as reprotoxic (it may damage fertility).

Warnings, markings and instructions

The checks performed by the MSAs on warnings, markings and instructions in their national language(s) revealed that 35% of the samples did not meet the requirements. The most common non-compliance issues detected were missing CE marks or CE marks that were an incorrect size and shape, missing information regarding a single point of contact and incorrect age warnings. Despite the fact that warnings, markings and instructions do not provide details on the chemical risk profile of the toys, they are an essential source of information for the parents/caregivers on the product and on its safe use.



4. Risk assessments and measures

4.1. Risk assessments

According to the TSD, toys placed on the Single Market shall comply with the essential safety requirements set out in the Directive. More specifically, toys shall not jeopardise the safety or health of users or third parties when they are used as intended or in a foreseeable way. When assessing whether a product poses a risk, the principles laid down in the Commission implementing decision (EU) 2019/417 laying down guidelines for the management of the European Union Rapid Information System (RAPEX Guidelines)⁵ should be respected.

These guidelines set out a risk assessment method that can be used by MSAs to assess the level of risk posed by consumer products to health and safety of consumers and to decide whether a Safety Gate notification is necessary. A specific Risk Assessment Guidelines tool, or 'RAG tool', for performing risk assessments (which takes into account the principles provided in the RAPEX Guidelines), is available on the RAPEX website and in the RAPEX application.

As regards products that are subject to restrictive measures by MSAs based on the presence of a chemical substance mentioned in the list of ingredients that is subject to restrictions contained in EU legislation but where there is no scientific data assessing the risk, notifications need to be assessed on a case-by-case basis.

However, an individual risk assessment is not necessary if:

- the presence of a chemical substance that is banned or present in a concentration above the limit established by European legislation (e.g. REACH) is detected;
- if these limits are based on a scientific opinion that shows that the presence of this chemical poses a risk to the health and safety of consumers.

4.2. Corrective measures

Based on the test results and the checks performed on warnings, markings and instructions, the MSAs decide which corrective measure have to be taken regarding the products that do not comply with EU legislation and/or the applicable standards. *Figure 8 - Measures adopted for samples that did not meet the requirements (N=35)* illustrates the main measures taken.

Furthermore, when a serious risk is identified, MSAs are legally obliged to submit a notification in Safety Gate (pursuant to Article 12.1 of the General Product Safety Directive (2001/95/EC)⁷). The RAPEX Guidelines also recommend submitting notifications regarding measures taken against products posing a less than serious risk.

Following the actions triggered by the joint testing campaign (up to 14 April 2023), two products were subject to Safety Gate notifications, and notifications for another three products are pending.

Four of the eight samples that did not meet the requirements of the chemical testing were evaluated as posing a serious risk without an individual risk assessment being performed by the MSAs. The remaining four samples were individually risk assessed by the responsible MSA, which, by taking into account both the hazard and the exposure, decided assess the samples as posing a high risk⁶.

Figure 7 - Overview of risk levels for samples that did not meet the requirements (N=35)

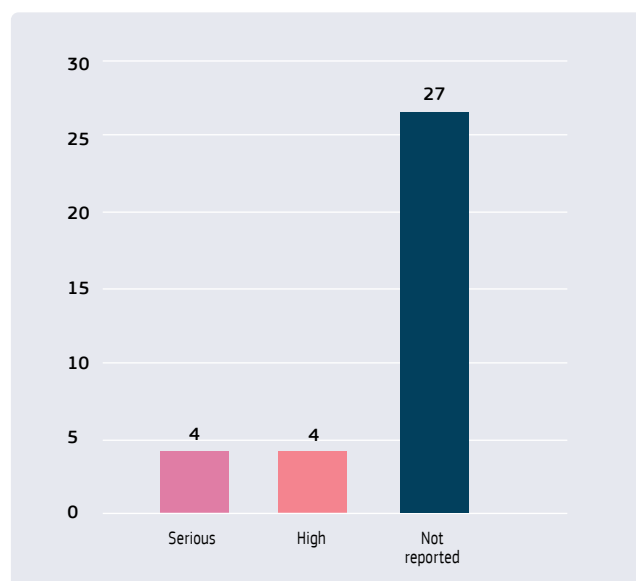
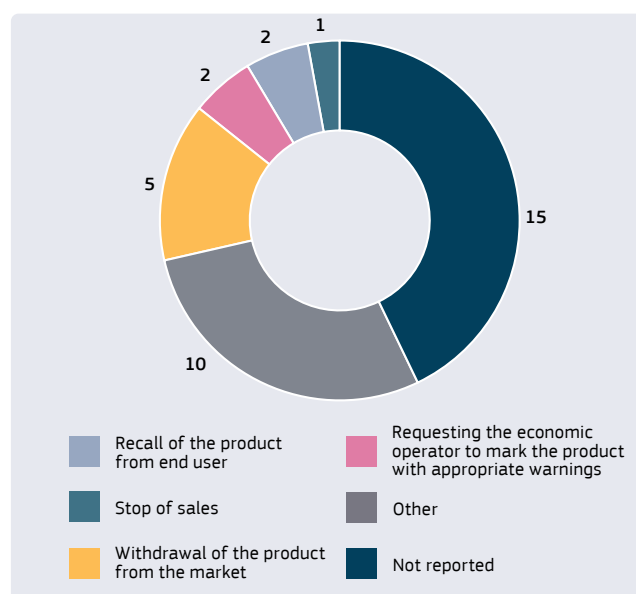


Figure 8 - Measures adopted for samples that did not meet the requirements (N=35)



⁵ Commission Implementing Decision (EU) 2019/417 of 8 November... – EUR-Lex (europa.eu)

⁶ The risk level of the samples that did not meet the requirements of the checks on warnings, markings and instructions was not indicated by the MSAs.

⁷ 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.

5. Conclusions and recommendations

5.1. Conclusions

Toys represent a product category in which MSAs invest remarkable resources and effort on a yearly basis due to the vulnerability of the consumers for whom these products are intended. The focus of an activity such as Chemicals in toys can be particularly broad, therefore, the MSAs participating in this PSA decided to concentrate on 37 hazardous chemicals that, based on their knowledge and experience, might have higher chances of being detected in toy products, especially those made of plastic.

The testing campaign detected phthalates and BPA in eight of the tested samples made either exclusively or partially of soft plastic. Although only 9% of the tested samples did not meet the requirements, the chemical risks related to the presence of phthalates and BPA that exceed limit values are serious. In fact, the banned phthalates tested for in this activity affect reproductive functions, interfere with the human hormonal system and may also cause asthma. Similarly, BPA is capable of altering the endocrine balance, especially in early childhood,

and it is classified as a substance with toxic effects on human reproductive capacity.

Furthermore, checks performed by the MSAs on warnings, markings and instructions in their national language(s) showed that 35% of samples did not meet the requirements. This is an important part of the risk profile of any product as it provides parents/caregivers with crucial information on a product's correct use and age suitability.

MSAs issued 2 Safety Gate notifications based on the outcome of this PSA (3 notifications are still pending) and asked the economic operators to withdraw the products from the market or recall them from the consumers when dangerous chemicals exceeding limit values were detected. For the samples that did not meet the requirements of the checks on warnings, markings and instructions, the MSAs mainly asked the economic operators to mark the products with appropriate warnings and to rectify the administrative non-compliances.

5.2. Recommendations for stakeholders

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

For consumers

Only purchase toys from trustworthy retail channels – online and offline. Do not look for cheaper products on other websites / retail channels as there is a higher chance that you will buy a lower quality product. Be careful **not to buy low-quality soft plastic toys**, they may pose a higher chemical risk.

Check that the toy bears the **CE mark** and the **name and physical address of a legal person established in the EU**. Make sure to carefully follow the **age warnings** on the toys.

Monitor younger children (under the age of 36 months) when they are playing with toys of older siblings which might be put in the mouth. Children under the age of 36 months tend to put toys in their mouth for a prolonged period of time and are more at risk when it comes to unsafe chemicals.

For European and national authorities

Keep focusing on chemicals in toys. Chemical risks are one of the most significant risks recorded in Safety Gate; MSAs are encouraged to use their intelligence networks and supporting communication networks to target and intercept chemically unsafe toy products. The permitted levels of hazardous chemicals in toys have been established based on the available scientific data and are tested according to the relevant 'state of the art' technology. Specific acute and chronic health problems are caused by unsafe chemicals in toys, such as long term and irreversible illnesses, toxic poisoning, cancer, and the development – or the intensification – of allergies that cause issues such as asthma.

Focus on soft plastic toys. Soft plastic toy materials such as soft PVC may contain the most problematic chemicals and it might be effective to focus surveillance on these materials. Based on the results of this activity, phthalate plasticisers were the most commonly detected chemicals, although other chemicals, such as BPA, detected in soft or semi-rigid plastic toys (for example bath ducks), may also be a problem.



For economic operators

Be aware of your obligations under the applicable legislation.

- **All economic operators** must act responsibly and in full accordance with the legal requirements of the TSD and REACH when making toys available on the EU market.
- **Manufacturers** must assess all chemical risks in relation to their toys and complete a documented conformity assessment before placing their toy products on the European market. This assessment must be retained by them or by their authorised European representatives in the form of technical files and in a declaration of conformity.
- **Importers** of toy products into the European market must first make sure that the manufacturer has completed a conformity assessment on the chemical safety of their toy products before placing them on the European market. Additionally, importers must make sure that the manufacturer's assessments are available in the form of technical files and in a declaration of conformity before they start placing toy products on the European market. Importers shall, for a period of 10 years after the toy has first been placed on the market, keep a copy of the EC declaration of conformity.
- Specifically for **online sales**, if there is no manufacturer, authorised representative or importer in the EU, the information must be retained by a **responsible person** or fulfilment service provider as appropriate.

Pay particular attention to toys made of soft plastic.

When performing risk assessments of plastic toys, be aware that soft plastic, in particular PVC plastic, may contain restricted substances such as phthalates. Additionally, BPA might be detected in soft or semi-rigid plastic toys (for example bath ducks).

Warnings, markings, and instructions.

- Product markings and labelling found on the toy must be in the national language(s) of the Member State where the product is made available. All conformity assessment documentation in the form of the declarations of conformity and the associated technical files must also be made available in a language easily understood by the relevant authority (as determined by the Member State concerned).
- Before being placed on the market, all toys must be labelled with the CE mark.
- All toys must carry the correct name and postal address of a European manufacturer and/or importer, and the appropriate traceability information to assist in the recall of unsafe toy products (a website is not sufficient for a contact point address). Be aware that if only the address of the distributor is included on the toy package, the latter bears full responsibility for the conformity assessment of the toy.

Know your supplier. Make a careful assessment when choosing who you work with. Verify and authenticate the identity of the suppliers you are dealing with.

Take measures when a toy product is found not to comply with EU's chemical safety requirements. Actively participate in the removal of unsafe toys from the market: this may very well include withdrawing or recalling the product immediately and alerting the public to the risk presented, in full cooperation with your distribution chain and with the MSAs.

Recalls. Clearly communicate with consumers on how they will receive information on possible recall actions. Make recall notices clear and accessible, and always indicate the hazards posed by the product. Regularly monitor the impact of a recall and adjust the strategy accordingly.

Report incidents to the competent authority. Where a toy presents a safety risk, economic operators have a legal duty to immediately inform the competent national authority of the Member State in which the toy has been made available. One method of notification is to use the [Product Safety Business Alert Gateway](#).



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

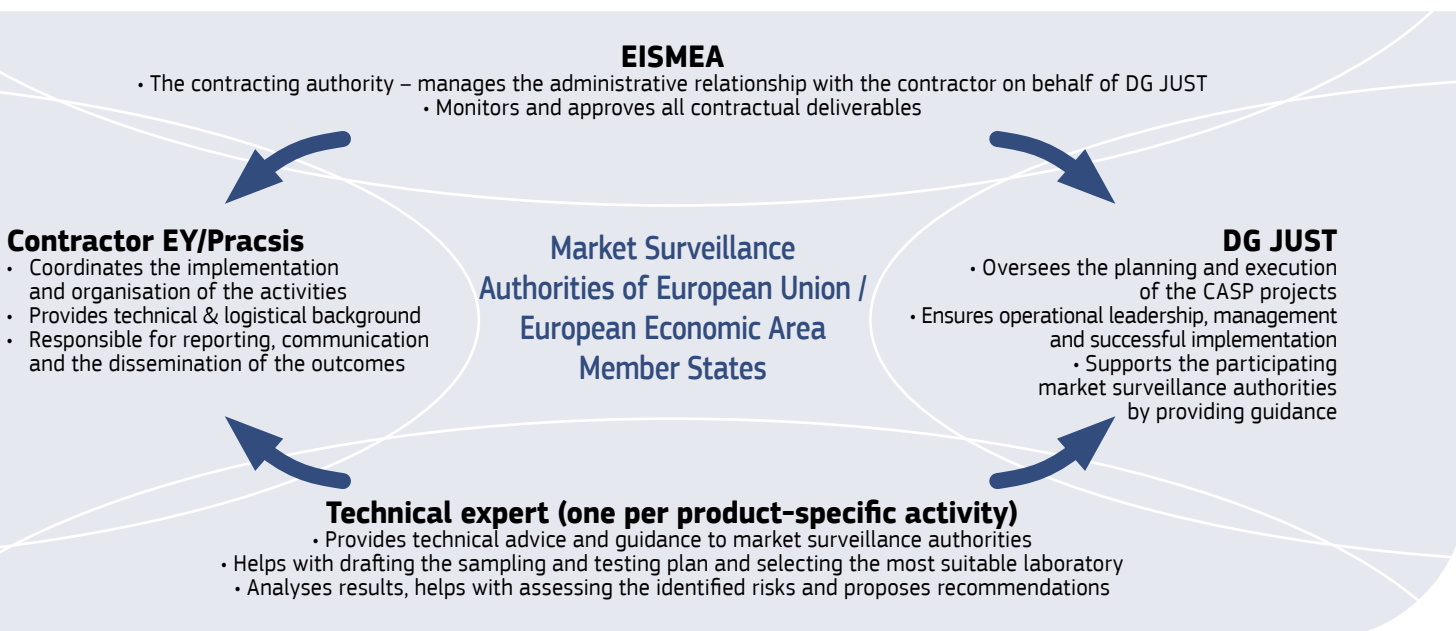
Product-specific activities test different types of products that may pose a risk to consumers. The products are selected and collected by the market surveillance authorities involved and are examined using a commonly agreed testing plan.



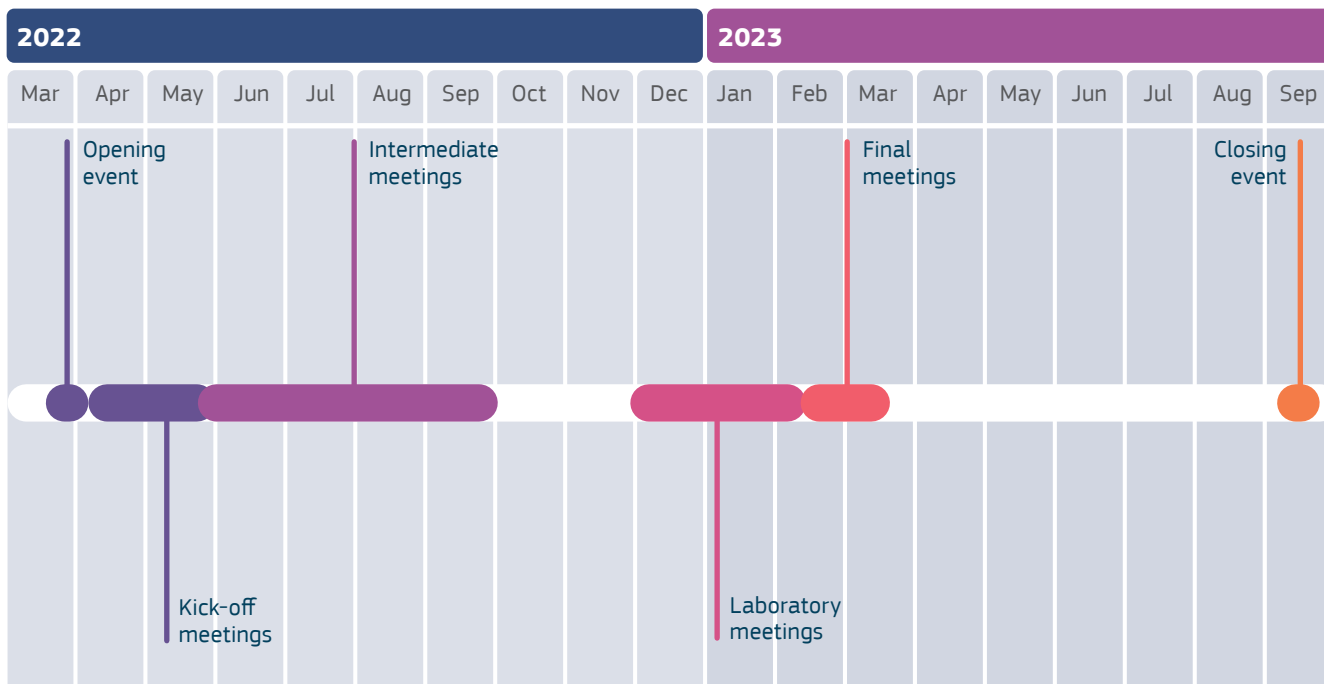
Horizontal activities provide a forum for market surveillance authorities to exchange ideas and best practices. Under the guidance of a technical expert, they develop common approaches, procedures and practical tools for market surveillance.



Roles and responsibilities



2. Product-specific activities work plan

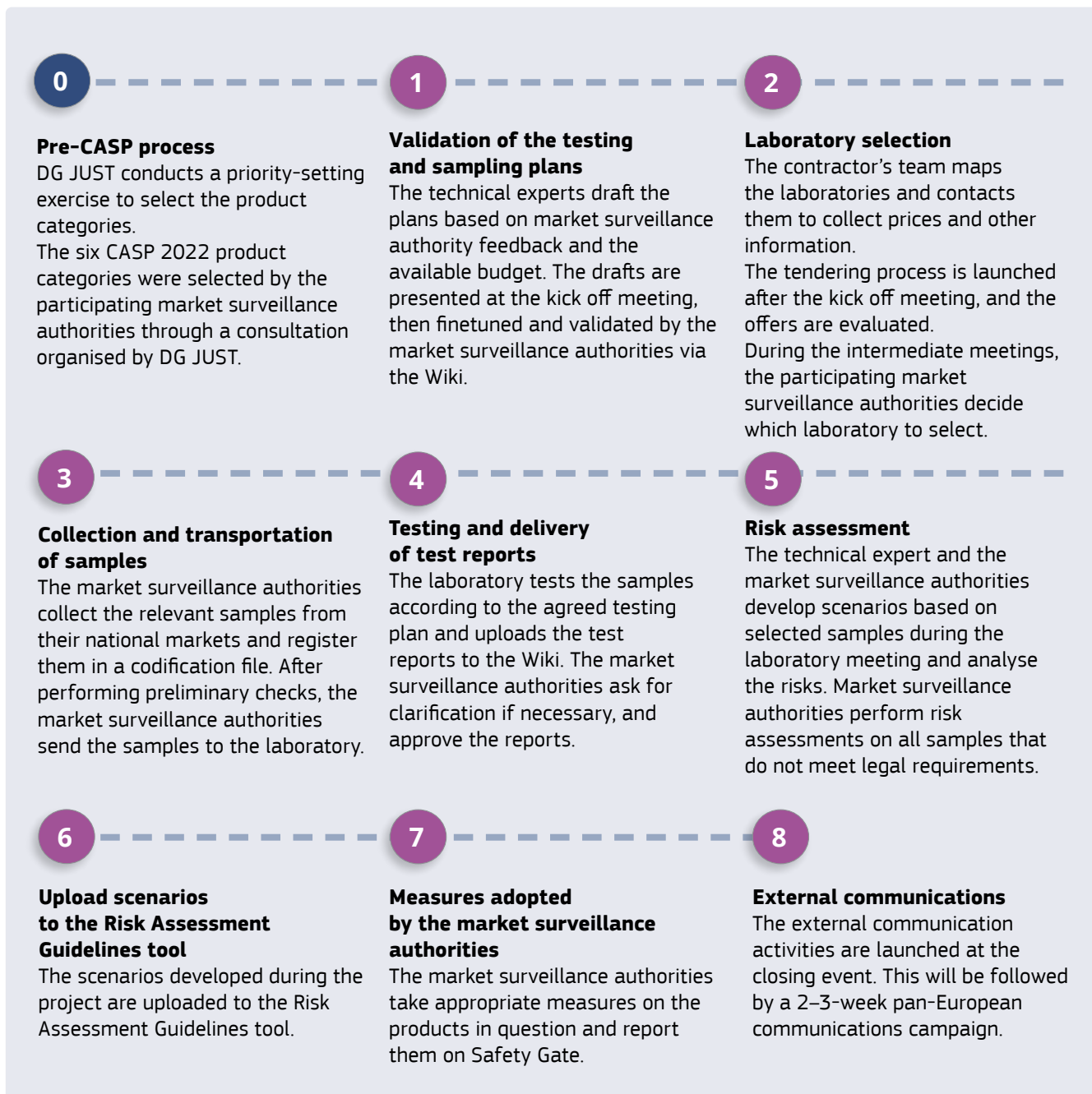


Continuous internal communication via the Wiki Confluence platform

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



Tools

Audio-visual clips addressed to consumers and a general audience are produced for each product-specific activity and the overall CASP 2022 project.

Infographics addressed to economic operators are developed for the CASP 2022 project, for each product-specific activity.

Final reports are produced for each activity and for the CASP 2022 project. They are translated into all official EU languages plus Norwegian and Icelandic.

Channels

The communication material is disseminated using:

- [The EC CASP website](#)
- Market surveillance authorities national communication channels
- Relevant press and other stakeholders

EUROPEAN COMMISSION

Directorate-General for Justice and Consumers
Directorate Consumers
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