ASASP | Association of Synthetic Amorphous Silica Producers

Webinar

Understanding SAS Harmonised Classification Proposal and Industry Impact

12 February 2026

A sector group of Cefic

European Chemical Industry Council - Cefic aisbl

EU TRANSPARENCY REGISTER N°64879142323-90

COMPETITION LAW

CHECKLIST FOR MEETINGS

DO

Ensure strict performance in areas on:

Oversight / Supervision

- Have a Cefic/Sector Group Secretariat representative at each meeting
- Consult with appropriate counsel on all questions which might be related to competition law
- Limit meeting discussions to agenda topics
- Provide each attendee with a copy of this checklist, and have a copy available for reference at all meetings

Recordkeeping

- Have an agenda and minutes which accurately reflects the matters which occur
- Ensure the review of agendas, minutes and other important documents by appropriate staff or counsel, in advance of distribution
- Fully describe the purposes, structures and authorities of the groups

Vigilance

- Protest any discussion or meeting activities which appear to violate this checklist
- Ask for those activities to be stopped so that appropriate legal check can be made by counsel
- Dissociate yourself from any such discussion or activities and for the attendees, leave any meeting in which they continue (and have it minuted)

This checklist is for the conduct of Cefic-sponsored meetings. Prohibited discussion topics apply equally to social gatherings incidental to those meetings. The checklist is not exhaustive.

Contact: Quentin Silvestre, Senior Legal Advisor at qsi@cefic.be

DON'T

in fact or appearance, discuss or exchange information not in conformity with competition law, including for example on:

Prices, including

- Individual company/industry prices changes, price differentials, discounts, allowances, credit terms, etc
- Individual company data on costs, production, capacity (other than nameplates capacities), inventories, sales, etc

Production, including

- Plans of individual companies concerning the design, production, distribution or marketing of particular products, including proposed territories or customers
- Changes in industry production capacity (other than nameplates capacities) or inventories, etc

Transportation rates

- Rates or rate policies for individual shipments, including basing point systems, zone prices, freight, etc

Market procedures, including

- Company bids on contracts for particular products; company procedures for responding to bid invitations
- Matters relating to actual or potential individual suppliers or customers that might have the effect of excluding them from any market or influencing the business conduct of firms towards them, etc
- Blacklist or boycott customers or suppliers

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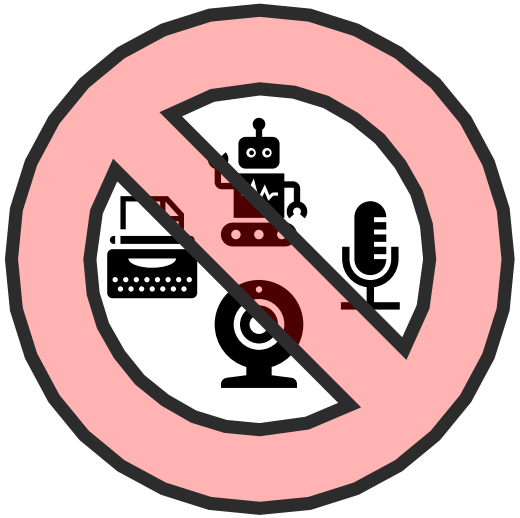

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Disclaimer

The information contained in this document is intended for guidance only and does not constitute legal advice. It summarises the interpretation of the classification of synthetic amorphous silica (SAS) by the Association of Synthetic Amorphous Silica Producers (ASASP). Other interpretations may also exist.

Whilst the information in this interpretation is provided in utmost good faith and has been based on the best information available at the date of publication, it is to be relied upon at the user's own risk. No representations or warranties are made with regards to its completeness or accuracy and no liability will be accepted by ASASP or any of its members for any loss, liability or damages of any nature whatsoever resulting from the use of this document and the information contained therein.

Housekeeping rules

Please ask your questions during the webinar using the provided QR code.
The code will be shared again during the Q&A session

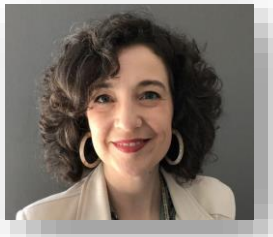
We will do our best to answer your questions at the end of the webinar.
You can also follow up in writing by emailing questions to asasp@cefic.eu

This event will be recorded

Today’s speakers

Sabrina Migliorini
Cefic - ASASP Manager & Particles Platform Secretary

Valérie Moise
ASASP Chair – EU Chemical Policy Director, Cabot



Emese Embersits
Cefic - Public Affairs Manager

Understanding SAS Harmonised Classification Proposal and Industry Impact

- Webinar agenda -

1) About Synthetic Amorphous Silica (SAS)
2) SAS CLH Classification Proposal
    - Background
    - ASASP Review of the RAC Opinion
    - Potential Impacts
3) What happens next?
5) Q&A

About ASASP

The Association of Synthetic Amorphous Silica Producers

- Cefic sector group established in 1992
- Promotes Synthetic Amorphous Silica (SAS) through open dialogue between industry and regulators
- Collaboration with leading scientists and academics
- Includes 9 member companies representing about 85% of the EU SAS industry

- ASASP is a partner of the Particles Platform that focuses on scientific and regulatory issues related to particulatre materials

About Synthetic Amorphous Silica (SAS)

What is SAS?

- Synthetic amorphous silica (SAS) is a manufactured, non-crystalline, highly pure, nanostructured form of silicon dioxide (SiO_2) that naturally forms aggregates and agglomerates
- Amorphous silica exhibits distinct safety and toxicological characteristics compared to crystalline silica
- SAS is available in various types, including pyrogenic (fumed), precipitated, gel, and colloidal dispersions
- SAS is a high-performance specialty chemical widely used across various industrial and consumer sectors
- SAS has been produced and marketed for nearly a century with consistent physicochemical properties

SAS – An essential ingredient in countless applications

Rubber & Tyres

Construction & Infrastructure

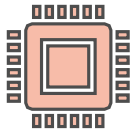
Batteries

Pharmaceuticals

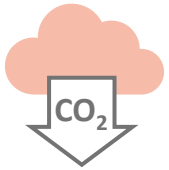
Food

Processing Aid

Silicone Elastomers

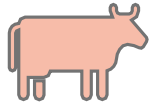


Electronics & Semiconductors



CO_2 Capture

Cosmetics & Personal Care

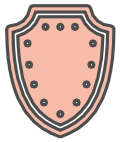


Feed

Packaging

Paints & Coatings

Technological Adhesives



Defence

ASASP Association of Synthetic Amorphous Silica Producers

Multiple functionalities of SAS in products

- SAS offers a unique combination of functionalities in the products it used in
- No alternatives can provide the same set of features in a single solution

Rubber & Tyres

Active reinforcing filler to enhance mechanical properties (tear & tensile strength, durability, and abrasion resistance)

Rheology control agent

Heat & Aging Resistance

Colour Retention / Transparency

Toothpaste

Customisable mild abrasive for plaque and stain removal

Thickening and rheology control agent to achieve desired toothpaste consistency, texture and viscosity

Biocompatibility SAS-fluoride: all fluoride stays soluble and available throughout brushing

Electrochemical Energy Storage

Anode: Buffers volume change

Separator: Enhances electrolyte wettability, improves mechanical strength

Electrolyte: Suppresses dendrite growth, boosts ionic conductivity

Scientific evidence continues to show SAS is safe in all applications

- Due to its broad use in numerous industrial and consumer applications, SAS is regularly assessed under different product-specific regulations and has consistently been confirmed to be safe

- ASASP member companies hold extensive expertise on SAS, built upon solid and long-standing technical knowledge of the substance

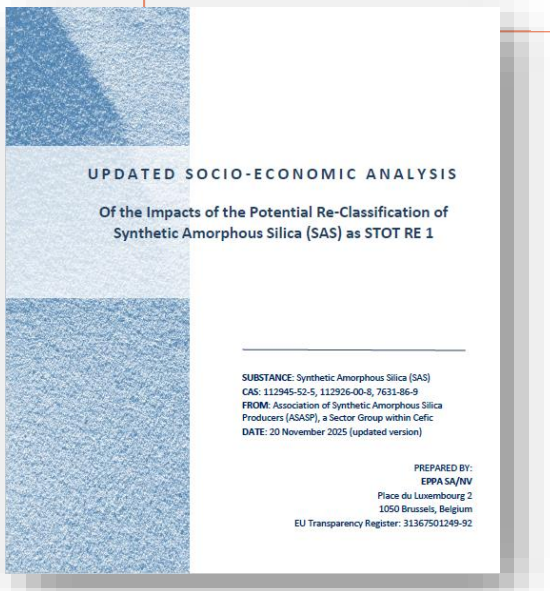
Food Regulation: The European Food Safety Authority (EFSA) has reconfirmed in 2024 the safety of SAS as food additive (E 551) across all its uses for all age groups, including infants under 16 weeks

Strategic importance of SAS for the EU

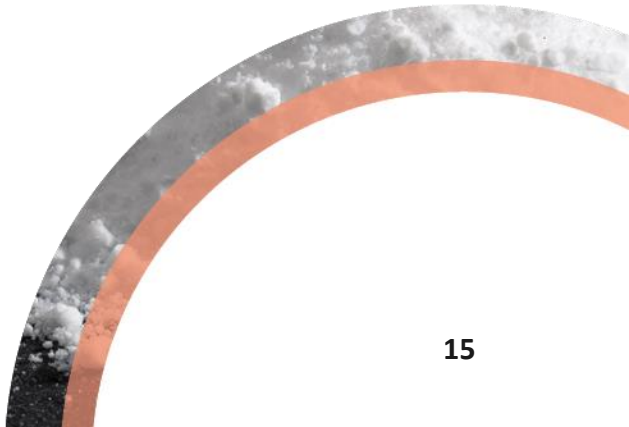
- SAS supports strategic EU goals:
  - **Autonomy** and decarbonisation
  - **Defence** resilience
- **20% of global production** is in Europe and EU is a **net** exporter
- Europe is the primary producer of **high-end technical grades** and the innovation leader around SAS
- Aggregated EEA business turnover related to SAS was more than **1.4 billion EUR** in 2024
- Downstream user sectors: combined estimated added value of more than **300 billion EUR** annually

European Production of SAS*

* Excluding colloidal silica



SAS Harmonised Classification Proposal



SAS CLH process and timeline 2024-2025

Outcome of the REACH substance evaluation process

The CLH process is carried out under CLP regulation to determine the EU harmonised hazard classification for a substance and its mixtures

June 2024	7 March 2025	27 October 2025
The Netherlands proposed to classify SAS as STOT RE 1 (respiratory tract) (inhalation)	ECHA RAC adopted its opinion, agreeing with NL classification proposal	ECHA RAC opinion published and sent to European Commission for decision

ASASP Actions:

- **2023-2024:** Submission of comments and data to Dossier Submitter (NL)
- **9 July 2024:** ASASP Downstream User Forum
- **June–Aug 2024**: Contribution to the CLH public consultation (> 70 submissions)
- **Throughout 2024**: Outreach to Member States Authorities
- **30 January 2025**: Participation to the RAC WG 72 meeting
- **2 October 2025**: Particles Platform Scientific Workshop
- **December 2025**: Meeting with the EU Commission

STOT RE 1: Specific Target Organ Toxicity by Repeated Exposure , category 1
CLH: Harmonized classification and labelling process
RAC: Risk Assessment Committee

ASASP concerns about the rationale of the proposal

- **SAS is a substance with no intrinsic toxicity**

  SAS shows reversible inflammation, caused by physical conditions, not intrinsic properties of the substance itself

- **The CLP regulation is not the appropriate tool to classify particles**

- **SAS is safe as placed on the market**

  Inhalation testing is not conducted on SAS forms as placed on the market

- **Rats are more sensitive to particles than humans**

  The anatomy of rat lungs make them prone to more severe inflammation

Particles Platform

- High scrutiny around particulate materials:
  - TiO_2, talc, SAS ….
  - Hundreds of materials potentially impacted
- Recent focus on harmonised classification proposals under the CLP:
  - Specific Target Organ Toxicity - Repeated Exposure (STOT RE)
- Approach has been problematic
- Informal alliance of EU industry associations across a broad range from chemicals to metals that joined forces to:
  - Understand the specificities of particulate materials
  - Find a workable and more focused approach under the umbrella of the Platform

www.particlesplatform.eu

2025 Scientific Workshop

Particles Platform

A proportionate approach to the regulation of particles based on the latest science

- Presentations and discussions focused on new scientific evidence and better approach to particle regulation
- High interest and participation from member states, national agencies, the Commission, ECHA, and industry
- Consensus on the scientific and regulatory complexity of particulate materials
- Identified challenges and gaps concerning particulate materials, including issues with OECD test guidelines, UN GHS and the greater sensitivity of rat lungs compared to humans
- Post-workshop recommendations with the creation of an ECHA Expert Group were presented at the January CARACAL meeting

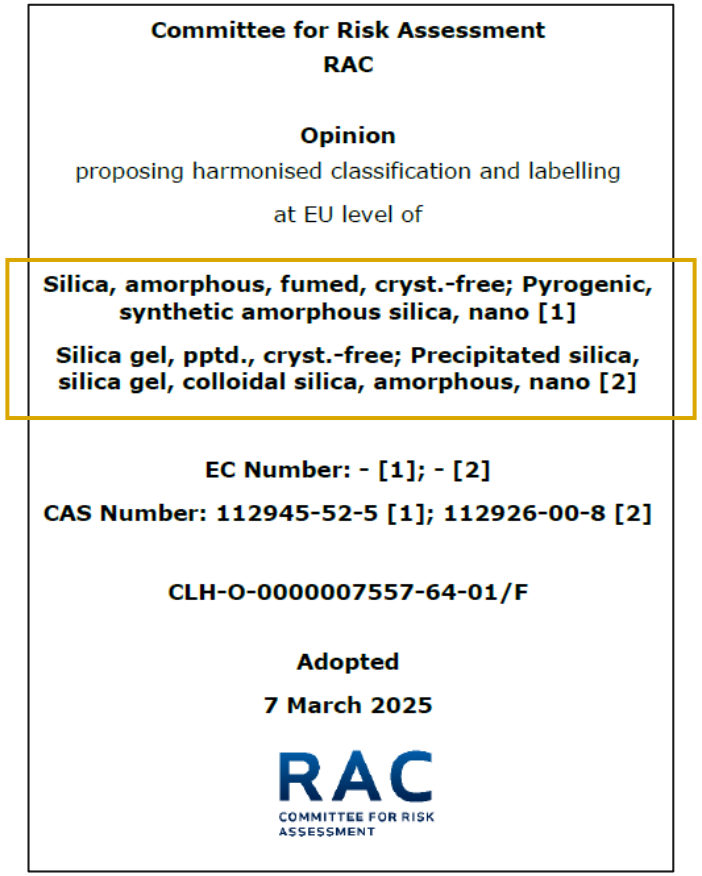
See Workshop Summary and Post-Workshop Recommendations

ASASP Review of the RAC Opinion

Issues of the RAC opinion on SAS

- **Substance identity and scope lack clarity**
  - Limited to nanoforms or includes both nano and non-nanoforms
  - Exclude natural amorphous silica
  - Confusion about the different types of SAS and their physical forms
  - Misunderstanding of SAS manufacturing process, structure, morphology and particle size

- **RAC numerous assumptions and assertions lacking supporting evidence**
  - *Even if rat and human lung clearance differ, effects in humans cannot be ruled out*
  - *Only inhalable SAS forms are considered relevant for classification*
  - *Some effects may stem from SAS surface reactivity, especially silanol groups*
  - *Adverse effects depend on surface OH-group density driving oxidative stress*



Committee for Risk Assessment
RAC

Opinion
proposing harmonised classification and labelling
at EU level of

Silica, amorphous, fumed, cryst.-free; Pyrogenic, synthetic amorphous silica, nano [1]

Silica gel, pptd., cryst.-free; Precipitated silica, silica gel, colloidal silica, amorphous, nano [2]

EC Number: - [1]; - [2]

CAS Number: 112945-52-5 [1]; 112926-00-8 [2]

CLH-O-0000007557-64-01/F

Adopted

7 March 2025

RAC
COMMITTEE FOR RISK ASSESSMENT

Issues of the RAC opinion on SAS (Cont.)

- **Basic Inaccuracies**
  - *Generic concentration limit (10mg/m³)* – should read 10% per CLP mixture rule (3.9.4)
  - *Aggregates size of SAS is mainly above 100 nm, but there is still a small fraction of respirable aggregates*

- **Interpretation of scientific data is not accurate and does not align with the scope of the CLP regulation**
  - Phys-chem. properties: surface chemistry and the role of the silanol groups, particle size
  - Severity assessment of the effects in the lung is missing
  - Interpretation of the CLP regulation : mixture rule, oversimplification leading to overclassification

- **Key information was not considered**
  - Data provided during the public consultation were not taken into account
  - Comprehensive human epidemiological studies demonstrating no adverse effects were dismissed

Issues of the RAC opinion on SAS - Summary

- **Substance Identity & Scope**
  A clear substance identity and a clear scope are essential for a RAC Opinion

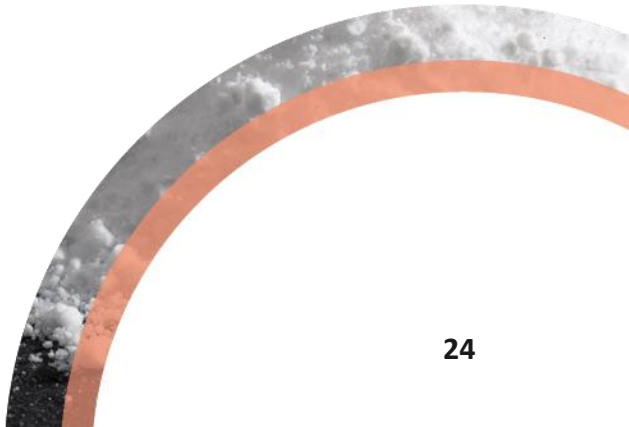
- **Assumptions and Assertions**
  Conclusions must be based on clear supportive evidence

- **Basic Inaccuracies**
  Basic inaccuracies and editorial issues have consequences on a good understanding of the Opinion

- **Errors & Interpretations**
  Clear and accurate interpretation of scientific data under the CLP framework is key

- **Information not Considered**
  Data submitted during the public consultation have not been taken into account

Potential Impacts of the Classification Proposal



Potential regulatory impacts

Decisions regarding classification must be grounded in a robust scientific basis due to their regulatory implications

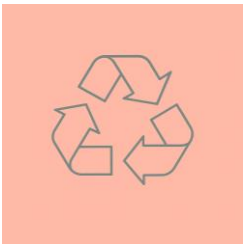
Occupational Safety and Health

- New workplace exposure controls required
- Compliance investments needed across multiple industries

CLP Regulation

- Increased administrative burden
- Exclusion by Downstream Users
- Re-labelling
- Mixture re-classification across sectors

Waste Framework Directive



- SAS-containing materials treated as hazardous waste
- Higher disposal and site-management costs across the supply chain

ESPR & Other Regulations

- Possible limitation on placing on the market of downstream products
- Some SAS-dependent applications, may face compliance issues. (e.g. Toys Reg.)

ESPR: Ecodesign for sustainable products regulation

ASASP position

- The RAC Opinion on SAS contains fundamental issues
  - Confusion around the substance SAS, the particles in general and the applicability of CLP regulation
  - Not all data provided have been considered to shape a robust weight of evidence approach

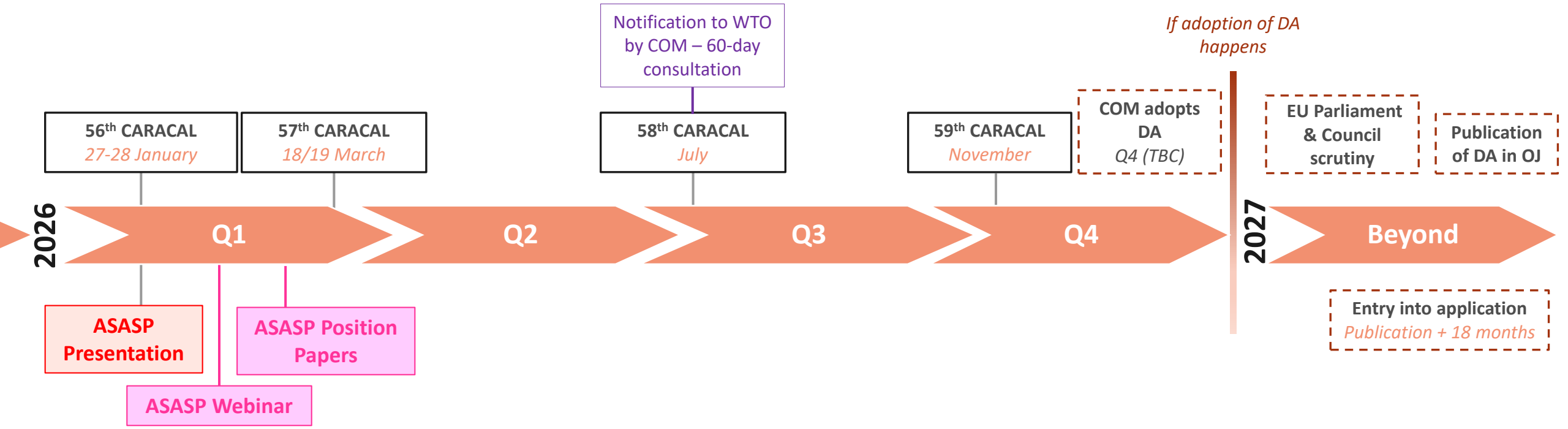
- A hazard classification will have significant regulatory and socio-economic impacts in the value chain without enhancing human health protection (workers and consumers)

Our request:

Address the scientific and regulatory complexities surrounding particulate materials before moving forward with the SAS classification process (ECHA Expert Group)

What happens next?

SAS CLH potential timeline



Active engagement with the European Commission

Active engagement with Member State Authorities

Collaboration Particles Platform

ASASP Association of Synthetic Amorphous Silica Producers

Conclusion

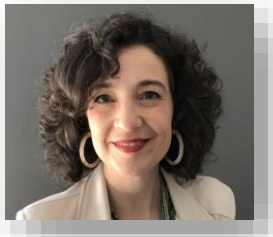
- The RAC Opinion is fundamentally flawed
- A comprehensive review of the RAC Opinion will be published shortly
- We maintain active collaboration with the European Commission and Member States authorities to emphasise the importance of a robust RAC Opinion
- ASASP member companies continue to demonstrate strong commitment to protecting human health and the environment
- We consistently promote a science- and evidence-based assessment of SAS, guided by expert knowledge on particles
- Your support—as downstream users, trade associations, and industry partners—is essential

ASASP Association of Synthetic Amorphous Silica Producers

Q&A

Sabrina Migliorini
Cefic - ASASP Manager & Particles Platform Secretary

Valérie Moise
ASASP Chair – EU Chemical Policy Director, Cabot



Jürgen Nolde
ASASP Vice-Chair – Director Global Product Stewardship, Grace

Emese Embersits
Cefic - Public Affairs Manager

Q&A

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Thank you

www.asasp.eu

https://www.linkedin.com/company/asasp-cefic

A sector group of Cefic

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