



European Precious Metals  
Federation

European Precious Metals Federation

# Silver Advocacy Task Force

3 February 2020 | Webinar

# Rules



**RESPECT  
COMPETITION LAW**



**KEEP  
CONFIDENTIAL**



**SHARE YOUR IDEAS**



# Agenda

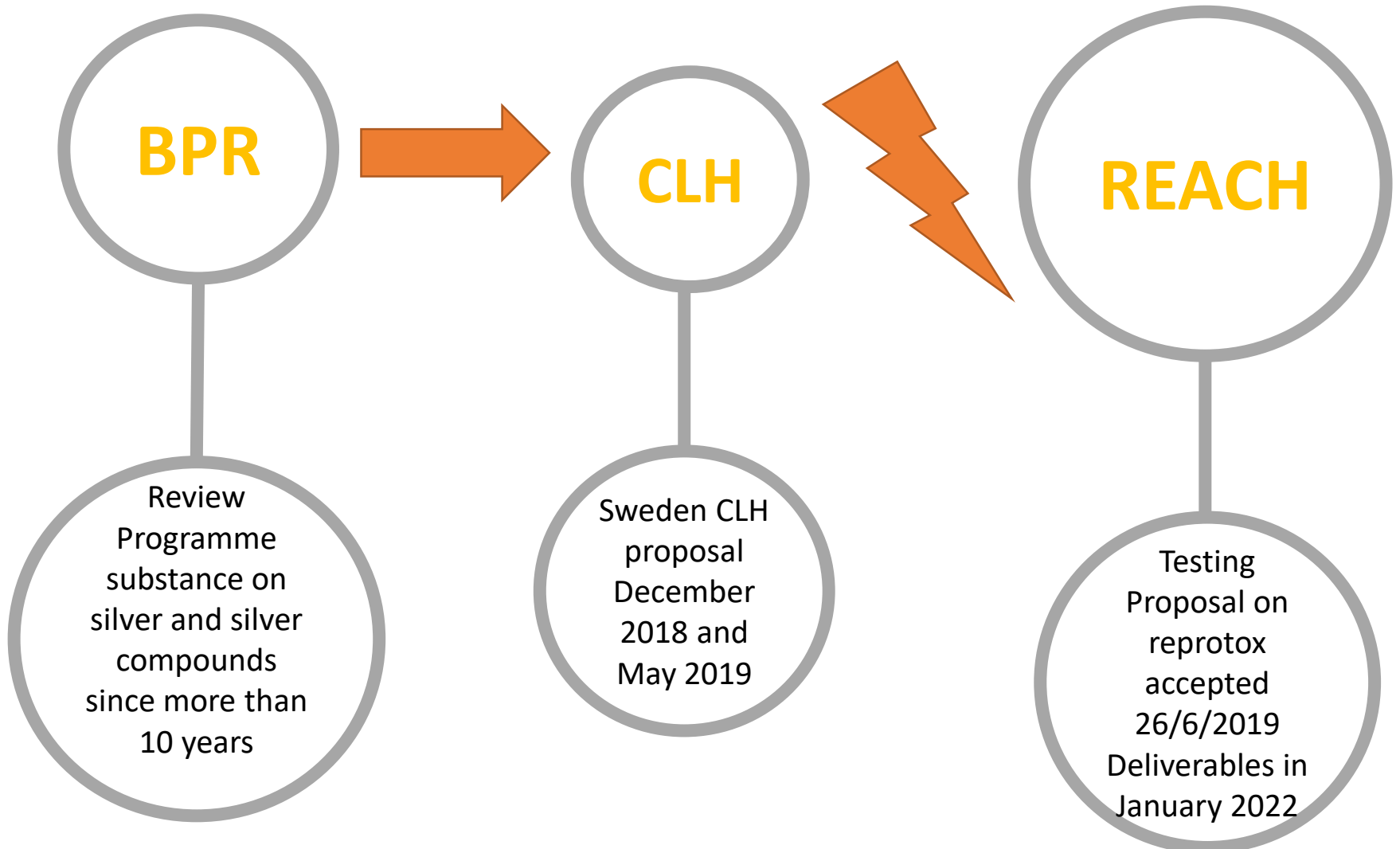
- Welcome and Introduction
- Status of silver and silver nitrate CLH proposal
- Status of the science:
  - TK and EOGRTs
  - Carcinogenicity data gap
- Eftec impact assessment: questionnaire
- Conclusions



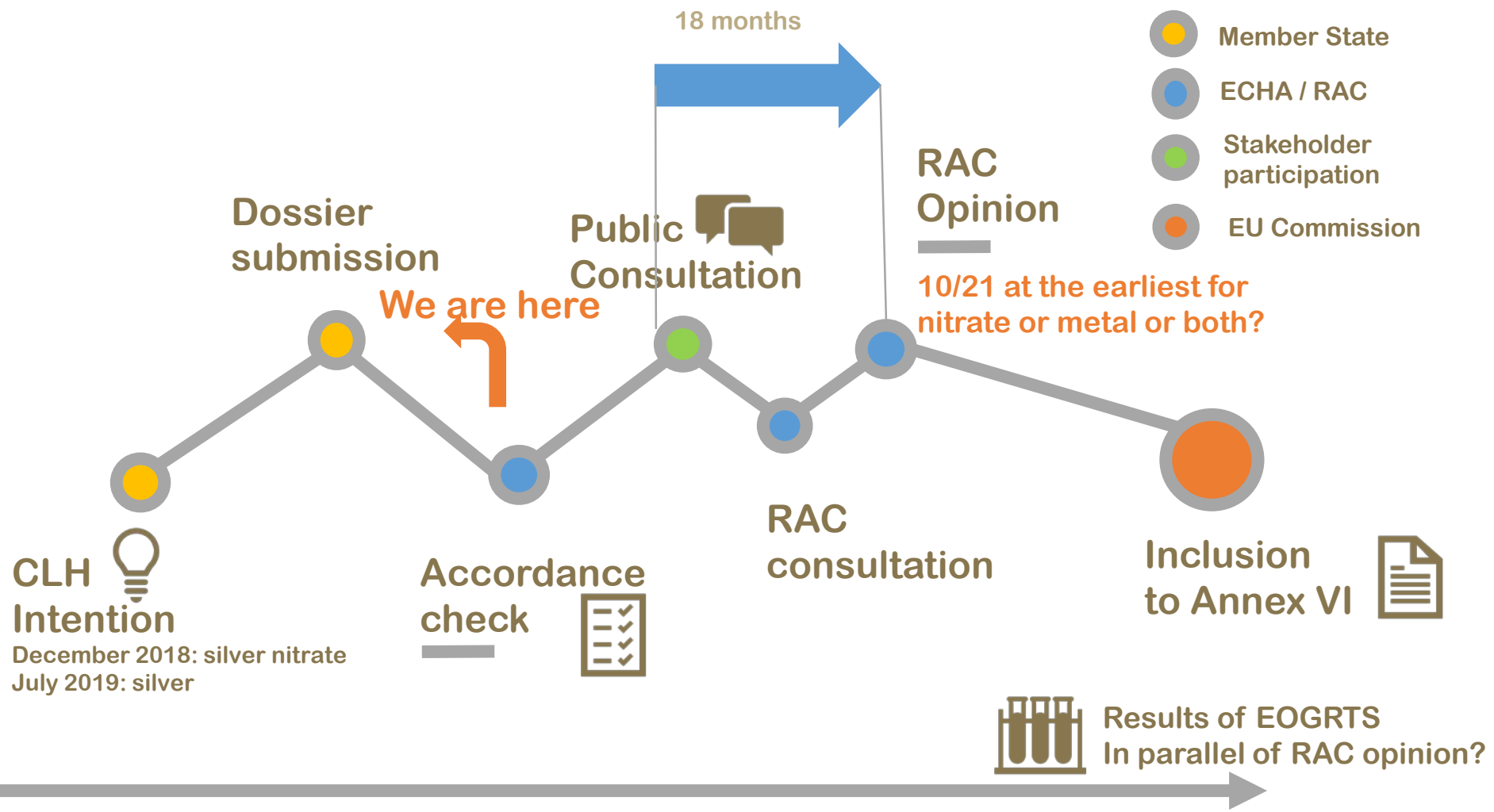


# State of play

# Interaction between REACH/CLH and BPR on silver



# Silver CLH Advocacy strategy: the process



# Impact on Advocacy first Milestone

**Success: Commission and ECHA agree to delay public consultation start**

**Timing: now to end Q1 2020?**

## Leverage scientific concerns

### Play to DG ENV and ECHA concerns

- Continue informal discussions

### Place on public record state of science

- Independent article on science around silver for placement in peer review journal

### Scientific symposium (2020)

- Symposium on first public results, TK results
- Trade media outreach

### Depending on when Kemi resubmits its CLH dossiers, re-engage with interested MSCAs from TP phase to encourage to submit to public consultation

- Reach out to PL, IT, FIN, DE

### Depending on when Kemi resubmits its CLH dossiers, Activate third country regulators to submit to public consultation

- Outreach to CH, NO, India, NZ, RSA, US, OECD

## Activate value chain

### Establish coordination mechanism with DUs

- Regular update calls scheduled
- Online Platform

### Promote broad participation in public consultation

- Prepare template for public consultation responses

### Prepare for joint outreach to MSs in next phase

- Map political and economic footprint – create joint DU/Silver teams
- Prepare materials pack for advocacy use by all actors (Strat on page, Messages, Q&A, Standard Deck, Summary of SEA)

## Elevate to political level

### Take the pressure off BPR - TBC

- Find policy dissonance/application that is under threat of interest to DG SANTE
- Outreach to DG SANTE hierarchy

### Underline benefits of silver

- Create visual representation of contribution of silver to VdL/European Green Deal political agenda
- Outreach programme to incoming cabinets around critical applications/positive policy agenda
- Outreach to MEPs as part of MetalsWithAmbition weeks





# Status of the science

## Toxicokinetics and EOGRTs (1)

- REACH registration dossiers Ag substances
  - Reprotox endpoint ~ multiple **uncertainties & data gaps**
    - test items in existing studies difficult to relate to effects Ag ion
    - no consolidated picture from studies on reproduction & fertility
    - no answer to existing questions on DIT (developmental immunotoxicology) and DNT (developmental neurotoxicology)
    - toxicokinetics (TK) often contradictory and fragmented
- Submission **Testing Proposal** (TP) for Extended One-Generation Reproductive Toxicity Study (EOGRTS) in 2015
- TP updated 2018 (reflect latest science)



## Toxicokinetics and EOGRTs (2)

- TP EOGRTS:

- OECD 443 guideline study
- Rat / dietary administration / silver acetate as test item

**Outcome of study anticipated to be applicable to ionic silver irrespective of donor silver substance forming this ion**

- Precautionary design:
  - incl. DIT & DNT-cohorts
  - integrating additional parameters (TK, micronutrient homeostasis etc.)

AIM: **accurate hazard assessment**

... but outcome **unpredictable** (i.e. risk of Repr 1B classification still exists)



## Toxicokinetics and EOGRTs (3)

- Testing strategy

**Issue 1:** generation **comparative TK data** via in vivo testing

- soluble Ag cmpds vs nanoAg vs Ag metal (as powder)
- quantify systemic circulation & distribution of Ag

AIM: strengthen **grouping** and **read-across** possibilities

**Issue 2:** clarify uncertainties and fill datagaps **reprotox**

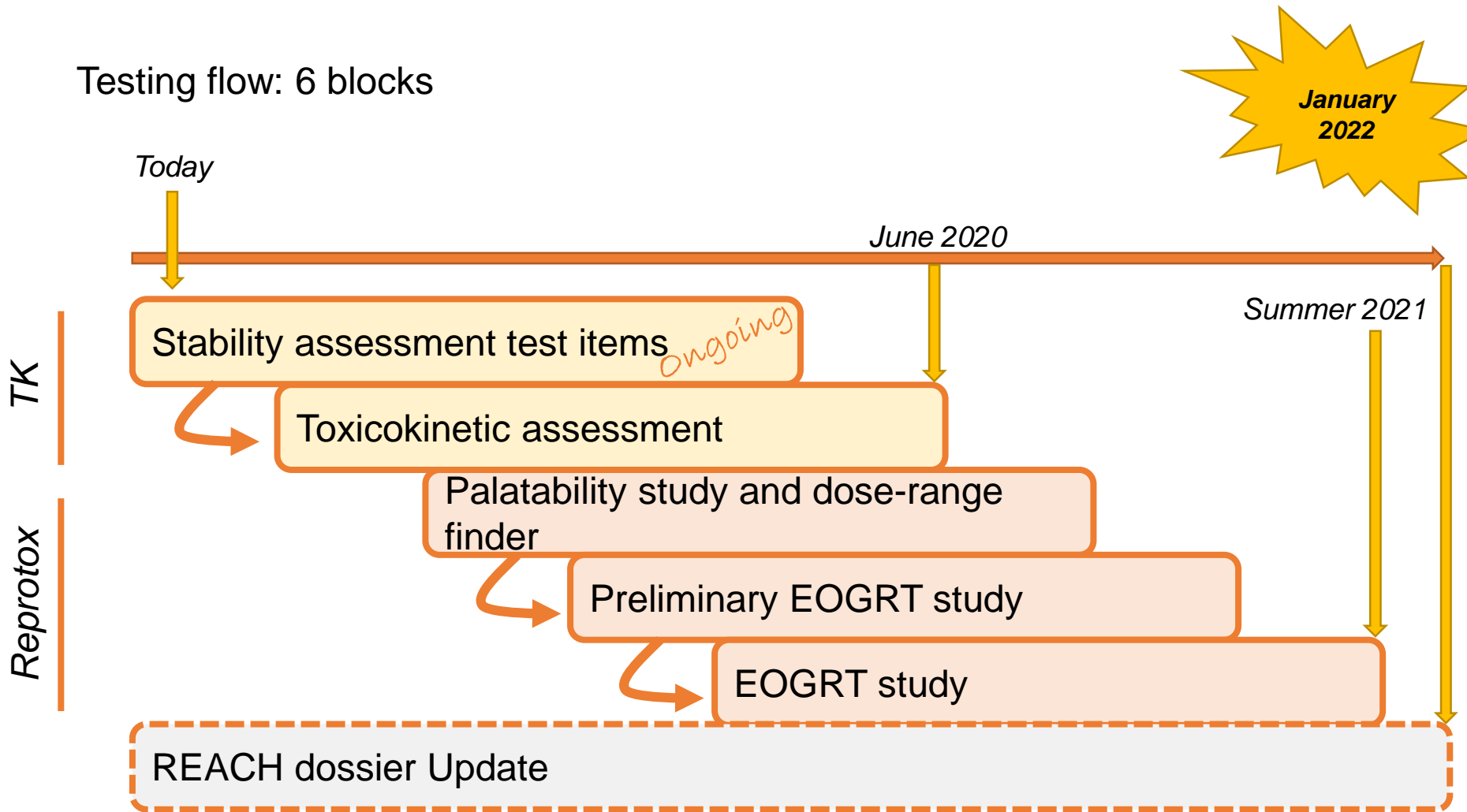
- Ag acetate as test item
- investigate effects on parental animals + offspring
- multitude of parameters assessed: reproductive & developmental endpoints, DIT & DNT cohorts

AIM: generate **solid** reprotox & developmental tox dataset



# Toxicokinetics and EOGRT

Testing flow: 6 blocks



# Carcinogenicity

- EPMF **REACH** dossiers
  - **no** carcinogenicity test data for Ag & Ag cmpds
  - **waiving statement** based on absence of
    1. mutagenic potential *and*
    2. reliable human data indicating any concern for carcinogenicity (despite long history of use)
- Silver Containing Active Substances (**SCAS**) registered under Biocidal Products Regulation
  - data requirements incl. human health endpoints
  - obligation evaluating member state (MS) to submit CLH-proposal
  - SCAS evaluating MS: Sweden (KEMI)



**Concern** identified for **carcinogenicity**



# Carcinogenicity

- SCAS dossiers: Experimental study (OECD453) for **SZZ** (Silver Zinc Zeolite)
  - concluded as **negative** by Risk Assessment Committee (Dec 2015)
  - CLP ATP 10: **no classification** for carcinogenicity (May 2017)

(iii) the following entries are inserted in accordance with the order of the entries set out in Table 3:

| Index No      | International Chemical Identification  | EC No | CAS No      | Classification   |                                       | Labelling                      |                               |
|---------------|--|-------|-------------|--|---------------------------------------|--------------------------------|-------------------------------|
|               |  |       |             | Hazard Class and Category Code(s)  | Hazard statement Code(s)              | Pictogram, Signal Word Code(s) | Hazard statement Code(s)      |
| *047-003-00-3 | silver zinc zeolite (Zeolite, LTA framework type, surface-modified with silver and zinc ions)<br>[This entry covers LTA (Linde Type A) framework type zeolite which has been surface-modified with both silver and zinc ions at contents Ag+ 0,5 %-6 %, Zn2+ 5 %-16 %, and potentially with phosphorus, NH4+, Mg2+ and/or Ca2+ each at level <3 %] | —     | 130328-20-0 | Repr. 2<br>Skin Irrit. 2<br>Eye Dam. 1<br>Aquatic Acute 1<br>Aquatic Chronic 1 | H361d<br>H315<br>H318<br>H400<br>H410 | GHS08<br>GHS05<br>GHS09<br>Dgr | H361d<br>H315<br>H318<br>H410 |

- **Read-across** applied between SCAS dossiers e.g. Silver Zeolite (SZ) and Silver Copper Zeolite (SCZ)

**CONCERN:** is read-across justified to **non-zeolite materials** like silver (metallic or reaction mass with SiO<sub>2</sub>), silver nitrate or silver sodium hydrogen zirconium phosphate?



# Carcinogenicity

- Read-across

Experimental study with  
'worst-case' test item

*Bridging data (like TK)*



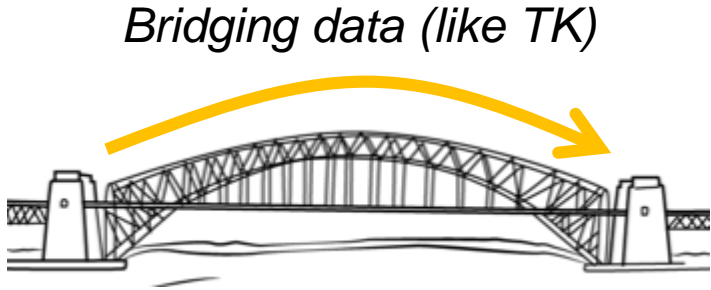
Read-across  
experimental data to  
other substances



# Carcinogenicity

- Read-across

Experimental study with 'worst-case' test item



Read-across experimental data to other substances

SZZ as worst case?

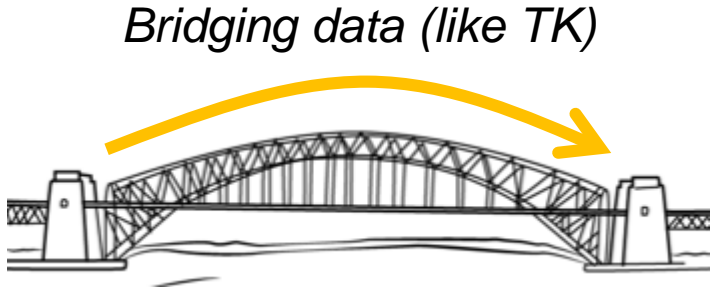
AgAc as preferred test item?

Study outcome?

# Carcinogenicity

- Read-across

Experimental study with  
'worst-case' test item



Read-across  
experimental data to  
other substances



SZZ as worst case?

TK data for SCAS?

AgAc as preferred test item?

TK data from our substances?

Study outcome?

Other data/studies available?

# Carcinogenicity

- Read-across

*Bridging data (like TK)*



Experimental study with  
'worst-case' test item

Read-across  
experimental data to  
other substances

SZZ as worst case?

TK data for SCAS?

What substances  
affected?

AgAc as preferred test item?

TK data from our substances?

Study outcome?

Other data/studies available?



# Carcinogenicity

## Preliminary conclusions:

1. SZZ **no worst-case** test item
2. **No** (comparative) **TK data for SCAS** exist, covering zeolite and non-zeolite materials  
→ read-across from SZZ to all SCAS **unlikely**
3. Request **new carcinogenicity test** under BPR very likely
4. Request for **'soluble Ag compd'** as test item very likely  
→ read-across to REACH dossiers **very likely**



# Carcinogenicity

- **EPMF action plan:**

1. Generation **comparative TK** data at EPMF
2. Commitment ESTF to generate **TK** data for **zeolite** material
3. Available data from

1. existing carcinogenicity study,
2. existing repeated-dose toxicity studies, and
3. existing evidence on genotoxicity/mutagenicity

**suggest absence carcinogenic potential** of silver

as technical input to KEMI / Biocidal WG together with ESTF (European Silver Task Force)

AIM: **try to avoid** the request for a carcinogenicity test

*ongoing*

*status?*

*done*



# Carcinogenicity

- **EPMF action plan:**

1. Generation **comparative TK** data at EPMF
2. Commitment ESTF to generate **TK** data for **zeolite** material
3. Available data from

1. existing carcinogenicity studies
  2. existing repeated dose toxicity studies, and
  3. existing genotoxicity/mutagenicity studies
- ... **carcinogenic potential** of silver

**... but final decision highly uncertain ... need to test anyway...?**

*...more clarity expected 2<sup>nd</sup> 1/2 February...*

as technical input to KEMI / Biocidal WG together with ESTF (European Silver Task Force)

AIM: **try to avoid** the request for a carcinogenicity test



# Impact Assessment of silver and silver compounds

Silver advocacy task force webinar / 3<sup>rd</sup> February 2020

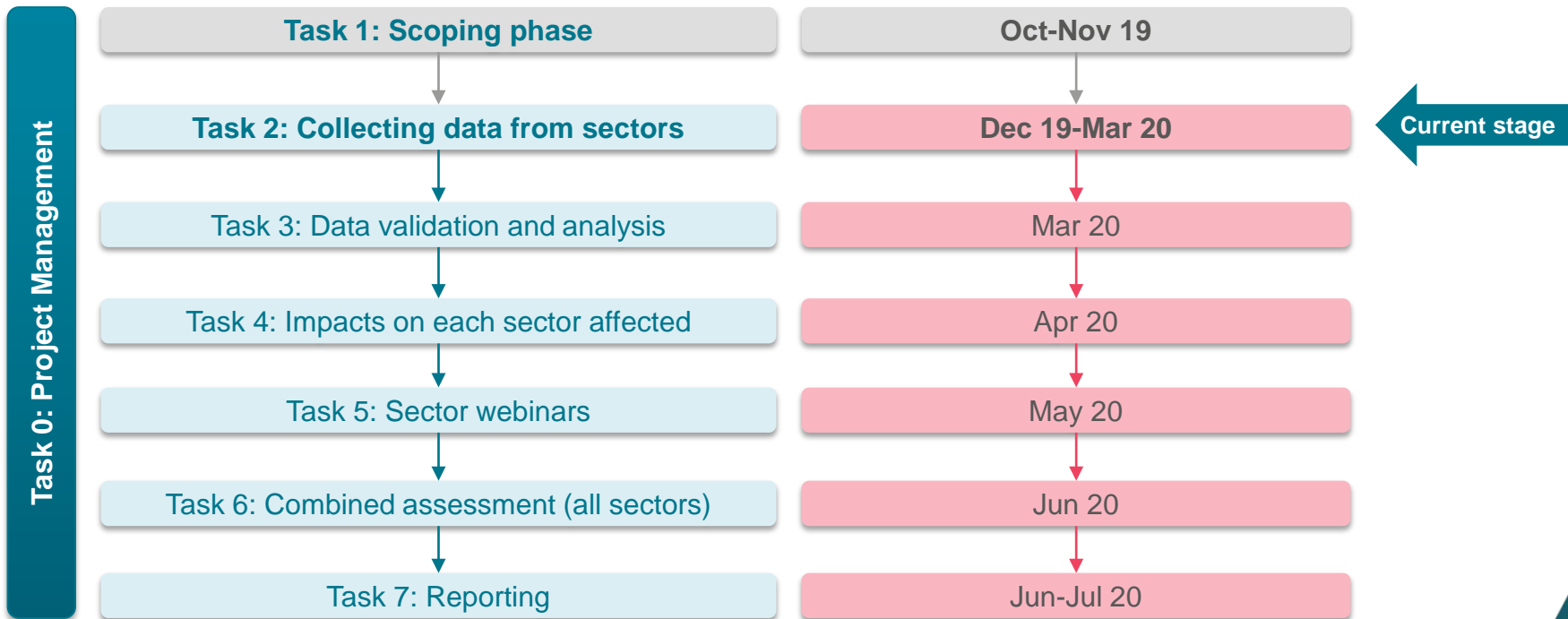
Rohit Mistry; Adams Koshy;  
Thea Sletten; Oliver Pilkington

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# Agenda

1. Overview of information request
2. Overview of questionnaire
3. Any questions?

# Project update



## What input do we need from you?

### Task 2

#### Dec 2019 - March 2020

1. ~~Two companies~~ to pilot test our survey and interview questions (Dec)

2. **All companies / associations** to fill in our survey (Jan-Mar)

3. **10 companies / associations** to take part in an interview (Jan-Mar)

### Task 3

#### March - April 2020

4. **All companies / associations** respond to queries we may have on your survey responses

5. **10 companies / associations** to confirm interview reports

### Task 5

#### May/June 2020

6. **All companies / associations** to read the specific chapter on your sector

7. **All companies / associations** to provide feedback at sector webinar and/or in writing

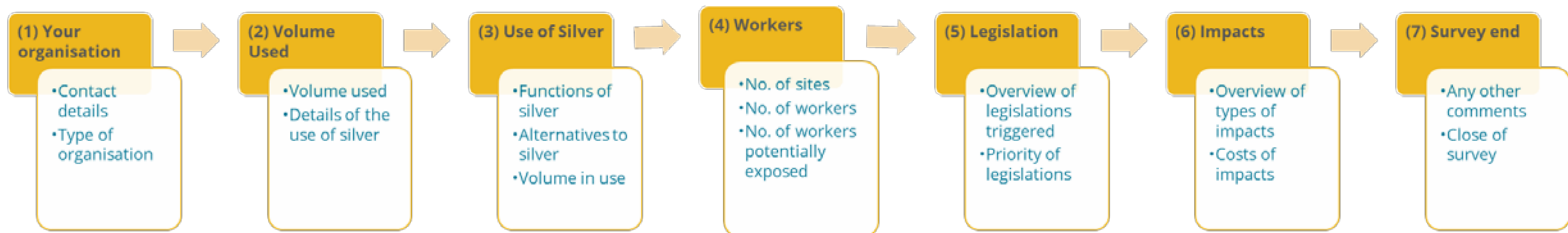


# Survey structure

## MI questionnaire



## DU questionnaire




# Functionality

**(2) Volume used** ← **The title of the tab**      **A short description about the tab**      **Description also includes the number of questions that will be asked in this tab**

The following questions are to help us collate information about the total volume of silver substances that are currently used in the European Economic Area (EEA) or Switzerland. This also refers to the volume of silver substances that is used internally by manufacturers/importers of silver. **This tab includes Q6 to Q9.**

**Q6. What volume of silver are used?** ← **The primary question**      **The secondary questions (Part A, B...)**      **Additional notes are often included in italics.**

| Silver substances<br><i>Please note there are <b>two parts</b> (A and B) to this question.</i> | A. Total volume (tonnes per year)<br><i>Mean 3-year annual average (2017 - 2019) within the EEA and Switzerland. Please provide information to the nearest tonne.</i> | B. Of the total volume DU - What proportion (%) is sold within the EEA and Switzerland?<br><i>Please provide information to the nearest percentage.</i> |                    |                   |       | Survey tips   |
|--|---|---|--------------------|-------------------|-------|---|
|  |   | Within EEA  | Within Switzerland | Rest of the world | Total |   |
| <i>EXAMPLE: Silver nitrate</i>   | 100   | 100%  | 0%                 | 0%                | 100%  |  |
| Silver metal   |   |   |                    |                   |       |   |
| Silver nitrate   |   |   |                    |                   |       |   |
| Silver carbonate   |   |   |                    |                   |       |   |

Most questions have a note on the number of parts it includes

At least one example is included to illustrate each question.

Cells that need to be completed will be shaded in green. They will go white when text has been entered into the cell.

Cells that are already in white or in grey cannot be completed.


Wherever possible additional survey tips will appear. Please pay close attention to these.

Please take note of any additional instructions to scroll to the right of the screen or down the screen.



# How to complete (5) Legislations

Click to expand

| 1  | A   | B  | C | D                               |
|----|---|--|---|---------------------------------|
| 2  | <b>(5) Legislations</b>   |  |   |                                 |
| 3  |   |  |   |                                 |
| 4  | The proposed CLP proposal (Repro 1B) will trigger a number of legislation that may have an impact on the <u>manufacture</u> of silver substance(s). We have identified 12 relevant legislation that could be triggered and may affect the manufacture and import of silver substance(s). We would like to |  |   |                                 |
| 5  | This tab includes Q13 and Q14.  |  |   |                                 |
| 6  |   |  |   |                                 |
| 7  | <b>Q13. How important are the legislations that will be triggered?</b>  |  |   |                                 |
| 8  |   |  |   |                                 |
| 9  | <b>A. What legislations will be triggered?</b>  |  |   |                                 |
| 10 |   |  |   |                                 |
| 11 | The following is the list of legislation that will be triggered as a manufacturer/importer of silver substance(s).  |  |   | Have you heard this legislation |
| 12 |  Survey tips: for more information on each legislation, please press the ungroup [+] button above column D.  |  |   | Please tick all t               |
| 13 | CLP Regulation  | This regulation is based on the United Nations' Globally Harmonised System (GHS). The overall objective of the regulation is to "[...] ensure a high level of protection of human health and the environment as well as the free movement of chemical substances, mixtures and certain specific articles, while enhancing competitiveness and innovation." (CLP, 2008, Article 1). CLP is legally binding across Member States and directly applicable to all industrial sectors. It requires manufacturers, importers or downstream users of substances or mixtures to classify, label and package their hazardous chemicals appropriately before placing them on the market. |   | <input type="checkbox"/>        |

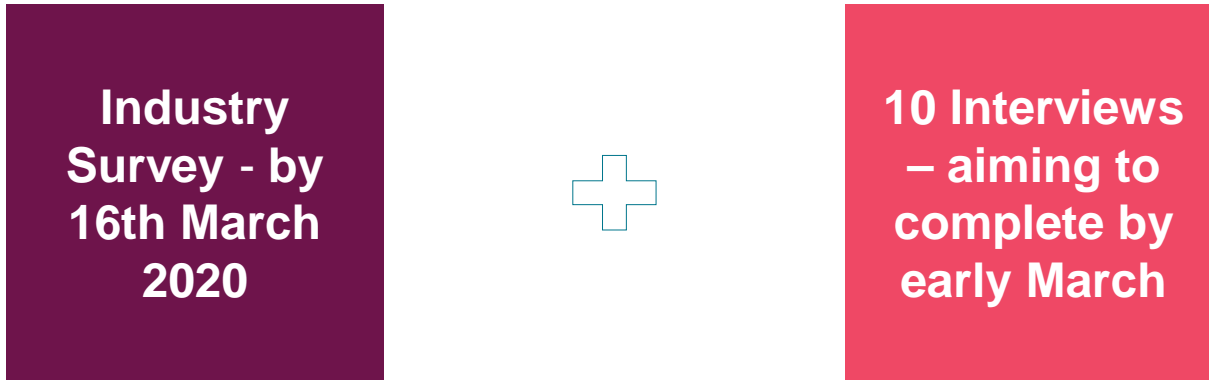


## Completing the survey for downstream users of silver-containing products

Please complete the following tabs of the **DU version of the survey**:

| Tab     | Approach   |
|---------|--|
| Tab (1) | ✓  |
| Tab (2) | Q7 is a priority; Q6, if information is available  |
| Tab (3) | ✓  |
| Tab (4) | Skip. Please note total number of workers in your site(s) that use the silver containing products in Tab (7) |
| Tab (5) | ✓  |
| Tab (6) | Only some questions will be relevant. Please consider each question from the context of your organisation    |
| Tab (7) | ✓  |

## Information request deadlines



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# Any questions?

Please also feel free to send any questions to

Adams Koshy ([adams@eftec.co.uk](mailto:adams@eftec.co.uk)) or France Capon ([france.capon@epmf.be](mailto:france.capon@epmf.be))

# Thank you

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# Conclusions



# THANK YOU

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