



# Ag Zn Zeolite - CLH

## Advocacy plan

### 1. Tentative timeline and key milestones



Key milestones for advocacy:

- RAC meeting: via Eurometaux
- EC discussion
- WTO notification
- REACH Committee recommendation
- EC final decision

### 2. Stakeholders mapping

Cf. Annex 1.

### 3. Key messages

#### Science

Cf. Bullet points in preparation of RAC in Annex 2.



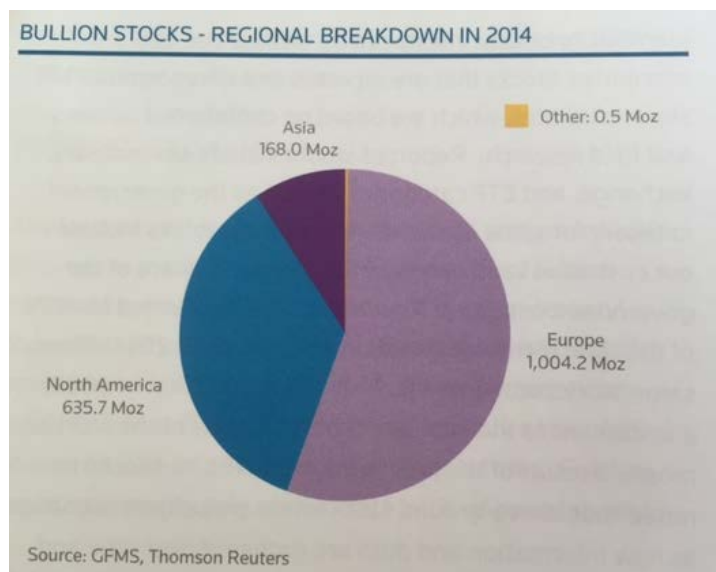
## Economic<sup>1</sup>

### EU Mine production:

<i>EU silver mine production</i>										
Million ounces	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Poland	40,5	40,5	39,6	39	39,2	37,6	40,8	41,3	37,6	40,6
Sweden	9,1	8,6	9,4	8,4	8,7	9,2	9,1	9,8	10,8	12,7
Portugal	0,8	0,6	0,9	1,3	0,7	0,7	1	1,1	1,4	1,7
Spain	0,2	0,1	0,1	0,1	0,1	0,7	1,1	1,2	1,3	1,3
Greece	0	0,8	1,1	1,1	0,9	0,9	0,8	1	0,9	0,9
Bulgaria	0,7	0,6	0,4	0,4	0,5	0,4	0,5	0,6	0,6	0,6
Romania	0,9	0,5	0,1	0	0,1	0,2	0,4	0,3	0,3	0,1
Ireland	0,2	0,2	0,2	0,2	0,1	0,2	0,4	0,3	0,3	0,1
Italy	0,1	0,1	0	0	0	0	0	0	0	0
<b>Total</b>	<b>52,5</b>	<b>52</b>	<b>51,8</b>	<b>50,5</b>	<b>50,3</b>	<b>49,9</b>	<b>54,1</b>	<b>55,6</b>	<b>53,2</b>	<b>58</b>

In 2014, 58 Million ounces (or 1644t) and represents 6,6% of the worldwide production.

### Supply from above-ground stock



N.B.: Europe is including here Turkey and Russia.

### Supply of silver from the recycling of old scrap

<sup>1</sup> All the facts and figures come from “World Silver Survey 2015”, The Silver Institute and Thomson Reuters.



<i>Supply of silver from the recycling of old scrap</i>										
Million ounces	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Germany	17,6	15,1	15,1	14,6	12,6	14,9	16,7	21,6	17,3	14,3
Italy	4,3	5,5	5,6	5,9	5,8	6,5	9,7	9,9	8,7	7,9
UK	11,6	10,9	11,2	10,9	10,2	6,4	11,3	9,8	7,2	5,6
France	4,1	4,5	4,6	5,1	5,5	6,2	7	5,9	5,2	4,9
Czech Republik	0,6	0,7	0,9	0,9	0,9	1,2	1,6	1,6	1,4	1,4
Austria	1,3	1,3	1,2	1,2	1,1	1,1	1,2	1,2	1,2	1,1
Spain	0,4	0,4	0,4	0,5	0,5	0,7	1,3	1,3	1,1	1
Poland	0,6	0,7	0,8	0,7	0,7	0,9	1,1	1,2	1	0,9
Netherlands	1,4	1,3	1,1	1,1	1	1,1	1,2	1,2	0,9	0,8
Sweden	1	0,9	0,9	0,9	0,8	0,8	0,9	0,9	0,7	0,6
Belgium	0,7	0,6	0,6	0,6	0,6	0,6	0,7	0,7	0,5	0,5
Denmark	0,5	0,5	0,5	0,5	0,5	0,5	0,5	0,5	0,4	0,4
Portugal	0,4	0,4	0,4	0,4	0,4	0,4	0,4	0,4	0,4	0,3
Hungary	0,1	0,2	0,2	0,2	0,2	0,3	0,3	0,4	0,3	0,3
Finland	0,4	0,4	0,3	0,3	0,3	0,3	0,4	0,4	0,3	0,3
Slovakia	0,1	0,2	0,2	0,2	0,2	0,2	0,3	0,3	0,3	0,3
Norway	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,2
<b>Total</b>	<b>45,4</b>	<b>43,9</b>	<b>44,3</b>	<b>44,3</b>	<b>41,6</b>	<b>42,4</b>	<b>54,9</b>	<b>57,6</b>	<b>47,2</b>	<b>40,8</b>

The past two years was marked by a significant decrease of the secondary production, which turns now around 1157 tonnes in 2014 (24,2% of worldwide production). The following reasons have been identified for the decrease of this production:

- The increasingly toughening and overlapping nature of regulatory rules has increased costs for refiners and across the scrap supply chain;
- There is a decline in available supplies of near-market stocks;
- With the EU economy slowly turning around, distressed selling (which had peaked in 2009 but which did persist in the southern members of the Eurozone in particular over the past few years) has largely stopped across the region;
- In last part as a result of the first three points, not only is supply to the existing players dropping but the number of players in the industry has also fallen (e.g. France and Germany);
- The contribution from photographic scrap continues to fall.

### *Silver bullion trade*

EU is traditionally one of the world's main deficit regions as fabrication demand exceeds mine production and supply from locally generated scrap and this remained the case in 2014. Part of this resulting gap was covered by imported scrap and silver stocks, but that still left room for imports of refined bullion, doré and concentrates.

Silver is also important in investments with the production of bars, coins and medals (around 100t are produced per year in the EU for this issue).

### *Industrial applications*



<i>Industrial applications</i>										
Million ounces	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Germany	23,9	25,5	27,4	27,5	20,2	26,5	25,4	21,7	21,3	21
UK	40,9	30,8	23,8	22	17,7	19,2	20,7	19	17,9	17,6
Belgium	26,6	29,2	27,8	24,3	19,4	17,6	14,3	13,2	11,9	11,3
Italy	10,9	10,9	11,3	11,2	9	9,9	9,2	8,6	8,4	8,4
France	10,2	10,4	10,7	10,8	7,5	8,8	8	7,2	7	6,8
Czech Republik	1,6	2,1	2,4	2,7	2,1	2,4	2,6	2,8	3	3,1
Netherlands	1,6	1,6	1,6	1,6	1,3	1,5	1,5	1,4	1,4	1,4
Spain	1,9	1,9	1,9	1,9	1,7	1,8	1,4	1,2	1,1	1,1
Poland	0,7	0,7	0,8	0,8	0,7	0,7	0,7	0,7	0,7	0,7
Austria	0,6	0,6	0,6	0,5	0,5	0,5	0,5	0,5	0,5	0,5
Norway	0,7	0,6	0,5	0,5	0,4	0,4	0,4	0,4	0,4	0,4
Sweden	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3
Romania	0,4	0,4	0,2	0,2	0,2	0,2	0,2	0,2	0,2	0,2
Hungary	0,3	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1
Portugal	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1
Slovakia	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1
Other countries	0,3	0,4	0,4	0,4	0,3	0,3	0,3	0,3	0,3	0,3
<b>Total</b>	<b>121,1</b>	<b>115,7</b>	<b>110</b>	<b>105</b>	<b>81,6</b>	<b>90,4</b>	<b>85,8</b>	<b>77,8</b>	<b>74,7</b>	<b>73,4</b>

In 2014, 2081 tonnes have been used in industrial uses in the EU. This represents 12,5 % of the worldwide industrial use of silver.

Main industrial applications are:

- Photovoltaic cells
- Brazing alloys and solder silver fabrication
- Ethylene oxide industry (as catalysts)
- Electronics
- Photography

The decrease during the past years is due to several factors:

- Substitution of silver by other metals for cost reasons;
- The substitution of gold by silver in some electronic applications declined;
- Fabrication of brazing alloys and electronics fell and this had consequences on the silver market;
- The decline of classical photography which has now probably touched the floor.

The drive towards new applications that could revive the usage of silver in industrial applications is strong, but so far no real significant breakthroughs have been recorded. Various promising technologies are on the horizon, of which one is related to LED applications that could find a wide adoption and have a positive impact on the demand for silver.

*New uses of silver in industrial applications*



As an introductory remark, it is important to note that, while the silver consumption per unit may be small in each application, their collective use may, over time, amount to substantial volumes.

Main uses are very often focused on utilizing its biocidal or conductive properties.

Biocidal properties:

- Antimicrobials
- Medical industry: antimicrobial coating in medical devices (aim minimizing infection)
- Active ingredient in burn therapy
- Water purification
- Household appliances
- “Smart clothing” for the biocidal but also conductive properties. This market could multiply from 24M\$ to 849M\$ in 2021.

Conductive properties:

- Transparent conductors (TCs): LCD displays, photovoltaic cells and touch screens: main material used so far is Indium Tin Oxide but silver is increasingly substituting it and especially in touch screens.

## Jewellery

<b>Jewellery</b>										
<b>Million ounces</b>	<b>2005</b>	<b>2006</b>	<b>2007</b>	<b>2008</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>
Italy	31,5	28,2	25,8	22,6	21,3	21,8	16,5	15,1	15,9	17,8
Germany	3,8	3,8	3,9	3,7	3,8	3,7	3,6	3,6	3,4	3,3
France	1,5	2,6	1,7	1,6	1,7	1,9	2,2	2	1,7	1,6
Spain	1,4	1,3	1,1	1,1	1,2	1,1	1,1	1	0,9	0,9
Poland	1,9	1,7	1,9	1,9	1,5	1,3	0,8	0,6	0,6	0,6
Greece	1,1	1,1	1	1,2	1	0,9	0,7	0,6	0,5	0,5
UK	1	1	0,5	0,4	0,4	0,4	0,4	0,3	0,3	0,3
Sweden	0,4	0,4	0,4	0,3	0,3	0,3	0,3	0,3	0,3	0,3
Portugal	1	0,9	0,7	0,6	0,6	0,6	0,4	0,2	0,2	0,3
Denmark	0,3	0,3	0,3	0,2	0,2	0,2	0,2	0,2	0,2	0,2
Netherlands	0,2	0,2	0,2	0,2	0,2	0,2	0,2	0,2	0,2	0,2
Norway	0,2	0,2	0,2	0,1	0,1	0,1	0,1	0,1	0,1	0,1
Other countries	0,9	0,8	0,8	0,8	0,6	0,6	0,6	0,6	0,5	0,6
<b>Total</b>	<b>45,2</b>	<b>42,5</b>	<b>38,5</b>	<b>34,7</b>	<b>32,9</b>	<b>33,1</b>	<b>27,1</b>	<b>24,8</b>	<b>24,8</b>	<b>26,7</b>

In 2014, 756 tonnes of silver have been used in Jewellery in the EU, which represents 12,5% of the worldwide production.

## Silverware



<i>Silverware</i>										
Million ounces	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Italy	8	7,2	6,6	5,5	4,6	4	2,8	2,3	2	1,9
Germany	3	2,9	2,7	2,3	1,6	1,6	1,4	1,1	1	0,9
Norway	0,9	2,6	1,7	1,6	1,7	1,9	2,2	2	1,7	1,6
Greece	1,5	1,4	1,2	1	0,8	0,6	0,5	0,4	0,3	0,3
Sweden	0,5	0,4	0,4	0,4	0,3	0,3	0,3	0,3	0,3	0,3
Denmark	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,2	0,2
UK	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,2	0,2	0,2
France	0,2	0,2	0,2	0,3	0,2	0,2	0,2	0,1	0,1	0,1
Finland	0,2	0,2	0,2	0,2	0,1	0,1	0,1	0,1	0,1	0,1
Other countries	1,1	0,9	0,8	0,6	0,3	0,3	0,2	0,2	0,2	0,1
<b>Total</b>	<b>16</b>	<b>16,4</b>	<b>14,4</b>	<b>12,5</b>	<b>10,2</b>	<b>9,6</b>	<b>8,3</b>	<b>7</b>	<b>6,1</b>	<b>5,7</b>

In 2014, 161 tonnes of silver have been used in silverware, this represents 9,3% of the worldwide market.

### Downstream Regulatory impact

If the silver zinc zeolite classification Reprotox cat 1B is attributed to the silver ion, silver and silver compounds could be classified as Reprotox cat 1B; as all the alloys containing 0,1% of silver. This will have a huge downstream regulatory impact. Indeed, the following downstream legislation will apply:

- REACH (EC N° 1907/2006 of 18 December 2006):
  - o the substance could be screened and identified as relevant SVHC, included into the Candidate list, and further prioritized and included into Annex XIV to REACH, as a substance subject to authorisation.
  - o the use of the substance on its own or in mixture can be restricted under a fast track procedure for consumer uses (REACH, art. 68.2 and art. 133.4)
- BPR (EC N° 528/2012):
  - o The use of substances classified as reprotox cat. 1B as active substance is excluded.
- CAD (Council directive 98/24/EC): OEL can be derived
- Pregnant & breastfeeding women at work (Council directive 92/85/EEC)
- Cosmetic products (EC N°1223/2009): use of reprotox cat 1B is prohibited.
- Toy safety (EC N°88/378/EEC): use of reprotox cat 1B is prohibited.
- Hazardous waste directive (Directive 2008/98/EC)
- Water (Directive 2000/60/EC): EQS can be set in priority.
- Food regulation and directives (e.g.: Food contact materials): use of reprotox cat 1B substance could be banned.
- Medical devices (2012/0266 (COD)): use of reprotox cat 1B substance is banned as mixture containing it.
- Ecolabel: Ecolabels are attributed to laptops and personal computers if CMR are not included, same for textiles etc.



## 4. Actions plan

What ?	Whom?	By when?
<b>1<sup>st</sup> phase</b>		
Draft key messages for EM	KA	1st week of September 2015
Informal discussion at ECHA	VV	2 <sup>nd</sup> week of September 2015
Draft letter for the MSCAs	FC	End of September 2015
Draft letter for the EC	FC	October 2015
Optional: meeting/call MSCAs	FC/KA	October-November 2015
Preparation of meeting with ECHA on envi	FC/KA/HW	October 2015
Discussion with ECHA on envi	HW	October 2015?
Preparation of RAC meeting with EM	FC/VV/KA/MR (optional)	November 2015
Debriefing from RAC meeting	FC/VV/KA	December 2015
Review of ECHA opinion to be sent to EC	FC/KA	December 2015
<b>2<sup>nd</sup> phase: Next steps in case of negative outcome</b>		
New letter to European Commission requesting for a meeting	FC	January 2016
Identification of key stakeholders on REACH Committee	FC	January 2016
Draft letter for WTO members who could be impacted by consultation	FC	January 2016
Alert DUs association	FC	Q1 2016
Meeting with European Commission	FC/KA/MR (?)/DUs?	Q1 2016
Contact REACH Cttee key stakeholders	FC/DUs sectors?	Q1 2016
Meeting with key WTO representatives in Brussels	FC/KA/DUs sectors?	Q1 2016
<b>3<sup>rd</sup> phase: depending on the outcome of Q1 2016 activities</b>		



## Annex 1: Stakeholders mapping

Stakeholders	Contact Persons			Contact person in industry/association	Comments	Status
	firstname	lastname	email			
<b>MSCAs</b>						
<b>Belgium</b>	Catheline	DANTINNE	catheline.dantinne@health.fgov.be	Umicore		
	Aurélié	DUSSART	aurelie.dussart@environment.belgium.be			
<b>Bulgaria</b>	Parvoleta	LULEVA	pluleva@moew.government.bg	KCM		
	Valeria	LEONKEVA	vleonkeva@mh.government.bg			
	Svetla	KRAPCHEVA	kraps@moew.government.bg			
<b>Finland</b>				Norilsk/Boliden		
<b>France</b>	Anne-Catherine	ALFANO	anne-catherine.alfano@developpement-durable.gouv.fr	Metalor	Comments submitted during the PC	
	Guillaume	BAILLY	guillaume.bailly@developpement-durable.gouv.fr			
	Corinne	BELVEZE	corinne.belveze@developpement-durable.gouv.fr			
	Emmanuel	MOREAU	emmanuel.moreau@ecologie.gouv.fr			
	Sophie	PAULTRE	sophie.paultre@developpement-durable.gouv.fr			
	Jordane	WODLI	jordane.wodli@developpement-durable.gouv.fr			
<b>Germany</b>	Theobald	ZIMMERMANN	theobald.zimmermann@hmulv.hessen.de	Fachvereinigung Edelmetalle/Heraeus/C.Hafner/BASF/Aurubis/Ferro/Doduco	Comments submitted during the PC	
<b>Italy</b>	Pietro	PARIS	pietro.paris@apat.it	Assomet/Safimet		
	PIETRO	PISTOLESE	p.pistolese@sanita.it			
<b>Luxemburg</b>	Paul	RASQUÉ	paul.rasque@mev.etat.lu	Commerzbank/Traxys		
<b>Netherlands</b>	Joke	HERREMANS	Joke.Herremans@rivm.nl	EPMF	Comments submitted during the PC	
	Hans	MEIJER	hans.meijer@minienm.nl			
	Dick	SIJM	Dick.Sijm@rivm.nl			



	T.H.M.					
	Jurgen	VAN BELLE	nj.v.belle@minvws.nl			
<b>Poland</b>	Dorota	DOMINIAK	dorota.dominiak@chemikalia.gov.pl	KGHM		
	Andrzej	KALSKI	andrzej.kalski@chemikalia.gov.pl			
	Ewa	LIBERSKA	ewa.liberska@chemikalia.gov.pl			
	Jerzy	MAJKA	jerzy.majka@chemikalia.gov.pl			
<b>Spain</b>	C.	CABALLO	ccaballo@msssi.es	Spanish federation/Sempsa		
	M.	BLARKA	mblarka@magrama.es			
<b>UK</b>	Keith	BAILEY	keith.bailey@defra.gsi.gov.uk	Johnson Goldsmith/Dupont Matthey/Ames	Comments submitted during the PC	
	Andrea	CAITENS	andrea.caitens@hse.gsi.gov.uk			
	Pierre	CRUSE	pierre.cruse@hse.gsi.gov.uk			
	Ian	DOYLE	ian.doyle@environment- agency.gov.uk			
	Duncan	EGERTON	duncan.egerton@defra.gsi.gov.uk			
	Jan	HARRIS	jan.harris@hse.gsi.gov.uk			
	andrew	MOORE	andrew.area02.moore@hse.gsi.gov.u k			
	Lindsay	PEPPIN	lindsay.peppin@hse.gsi.gov.uk			
	Alan	MORLEY	alan.morley@hse.gsi.gov.uk			
	Deb	TRAYNOR	deborah.traynor@hse.gsi.gov.uk			
<b>Austria</b>	Olivia	FALB- NADERER	olivia.falb@lebensministerium.at	Montanwerke Federation Brixlegg/Austrian		
	Renate	PAUMANN	renate.paumann@lebensministerium .at			
	barbara	PERTHEN- PALMISANO	barbara.perthen@lebensministerium .at			
	Martin	WIMMER	martin.wimmer@lebensministerium. at			
	Helmut	WITZANI	helmut.witzani@umweltbundesamt. at			
<b>European Commission</b>						
<b>DG Growth</b>	Klaus	Berend	klaus.berend@ec.europa.eu	EPMF		
	Valentin a	Bertato	valentina.bertato@ec.europa.eu	EPMF		



DG Environment	Bjorn	Hansen	bjorn.hansen@ec.europa.eu	EPMF		
	Cristina	de Avila	cristina.de-avila@ec.europa.eu	EPMF		
?						
<b>ECHA, DS and RAC co-rapporteurs (CANNOT BE DIRECTLY CONTACTED)</b>						
ECHA				Eurometaux		
DS: Kemi				Eurometaux		
RAC rapporteur				Eurometaux		
RAC rapporteur				Eurometaux		
<b>WTO</b>						
Australia				EPMF		
Canada				EPMF		
China				EPMF		
India				EPMF		
Mexico				EPMF		
Switzerland				EPMF/Swiss federation/Metalor/Argor/Px Group/Pamp		
US				EPMF/IPMI/Silver Insitute		
<b>DUs sectors</b>						
Coins and Bars	Ruth	Crowell	Ruth.Crowell@lbma.org.uk	EPMF	LBMA	
Jewelry	Ashish	Deo	ashish.deo@responsiblejewellery.com	EPMF	RJC	
Electronic	Julian	Lageard	julian.lageard@intel.com	EPMF	Digital Europe	
Brazing alloys and solders						
Photography				Agfa Gevaert	Imaging and Printing Association (I&P Europe)	
Photovoltaic						
Silverware	Mauritz	Demeyere	<a href="mailto:m.demeyere@demeyere.be">m.demeyere@demeyere.be</a>	EPMF	FEC	



## Annex 2: Bullets points in preparation of RAC

### Comments on the Proposal for Harmonised Classification and Labelling for Silver zinc zeolite (SZZ)

By the Precious Metals and Rhenium Consortium (PMC)

#### Key messages human health hazard assessment

- The PMC does not agree with the proposed classification on **carcinogenicity** for SZZ for the following reasons:
  - Supporting evidence for the Carc. classification is mainly based on the finding of a positive trend for leukemia in an oral route lifetime study in one species (F344 rat). Interpretation of the occurrence of leukemia in the F344 rat is particularly problematic, such that many reviewers have questioned its relevance in this rat strain to human risk assessment.
  - A mouse bioassay performed on SZZ did not provide any supporting evidence of carcinogenic potential.
  - None of the individual constituents of SZZ (LTA zeolite, zinc and silver) have previously been associated with clear carcinogenic effects in either experimental animals or humans.
- The PMC does not agree with the proposed classification on **reprotoxicity** for SZZ for the following reasons:
  - Hazard classification of SZZ for developmental toxicity based on read-across from effects observed in studies with inorganic “silver” is not justified, since the observed effects are secondary to non-specific disruption of maternal homeostasis.
  - Oral exposure of rats to high doses of an inorganic Ag substance inadvertently causes a massive shift in intestinal microbiota, especially several enterobacterial sub-populations are diminished, resulting in severe gastroenteritis and thus contributing to a general disruption of homeostasis with an impairment of ETE metabolism on a broad scale (not restricted to Cu alone) in the intestinal tract.
  - In addition to the above, embryotoxic effects of AgCl were experienced in rats during dietary administration of a very high dose of 188 mg Ag/kg bw during the entire period of gestation (Shavlovski et al., 1995); however, this must not be considered a direct effect of Ag ions on embryogenesis, but instead represent a “secondary non-specific consequence” of the disruption of systemic Cu homeostasis in dams resulting in Cu deficiency<sup>2</sup>. This secondary

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<sup>2</sup> Disturbed Cu homeostasis in dams is accompanied by the formation of a Ag-modified, functionally inactive ceruloplasmin lacking Cu transport function. Thereby, the availability of Cu to the fetus is reduced because plasma ceruloplasmin is the main source of Cu for placenta and fetus



trace element deficiency in offspring does not constitute evidence for specific developmental toxicity of Ag ions.

- Comparing the findings of oral repeated dose toxicity studies of the silver-substituted zeolites SZZ and “silver containing active substance 2” as well as of unmodified zeolite A, it becomes obvious that the histopathological effects which determine the NOAELs from these studies originate from the non-substituted (unmodified) zeolite moiety itself, and that the modification of zeolite with silver does not have any appreciable influence on the toxicological effects.
- Overall, **based on the available mechanistic information and the considerations given in the CLP guidance with respect to classification for developmental toxicity in the presence of maternal toxicity through “secondary non-specific mechanisms” related to the disruption of maternal homeostasis, it is not considered justified to use the Shavlovski data on AgCl (1995) in support of classification of Ag substances for developmental toxicity Category 1B or Category 2.**
- The PMC has the following comments on the classification on **Specific Target Organ Toxicity Repeated Exposure (STOT-RE)**:
  - The repeated dose toxicity studies on silver and/or zinc modified zeolites summarised in the CLH report cover some consistent treatment-related effects, including histopathological changes in the kidneys.
    - Adverse effects in the kidneys and urinary bladder have been consistently reported in repeated dose studies with non-substituted zeolite A. In particular, deposition of crystalline material in the kidney and the excretion of this material via the urine may cause mechanical damage in the kidney and bladder associated with epithelial hyperplasia in these organs.
    - Based on the toxicity study dataset available for simple silver substances, the kidney does not appear to be a target organ.

Hence, there is a good basis to conclude that the **renal changes, including hydronephrosis, observed with silver zinc zeolite can be attributed to the zeolite moiety.**

- The pattern of **tissue pigmentation** observed in the various repeat dose toxicity studies following treatment with SZZ is consistent with the deposition of insoluble Ag complexes. In relation to the CLP endpoint criteria, **a robust basis for the assignment of a STOT-RE classification in respect of this phenomenon is lacking**, as it was not clearly correlated with significant attendant toxicity in terms of pathological or functional change. The weight of evidence from the historical database of investigations on such tissue-associated silver precipitates (see for example Landsdown, 2010) which includes mechanistic studies of argyria, indicates that such deposits are inert and not associated with pathological damage.



## Annex 3: Letter template for Q4 2015

Brussels, ....

Dear Sir or Madam,

The European Precious Metals Federation (EPMF - <http://www.epmf.be>) represents the interests of its member companies and national associations vis-à-vis the European authorities on several topics of relevance for the precious metals (PM) sector such as the safety of chemicals and waste management; access to raw materials, recycling and sustainability, including responsible sourcing; energy and climate change; trade, customs, tax and competitiveness; etc. The European Precious Metals and Rhenium Consortium (PMC - <http://www.epmf.be/index.php/reach-consortiumleft>) is hosted by the EPMF and is in charge of the REACH implementation for the Precious Metals industry.

We would like to draw your attention on a proposal of harmonized classification and labelling submitted by Sweden (Kemi) in April 2015 to classify silver zinc zeolite as inter alia carcinogen cat. 2, toxic to reproduction cat. 1B and STOT RE cat. 2. During the public consultation, EPMF submitted comments to challenge this classification proposal and especially the fact that the reprotox effect was attributed to the silver ion (for more information on EPMF comments: <http://echa.europa.eu/harmonised-classification-and-labelling-previous-consultations/-/substance-rev/9302/term>).

In addition to the fact that the scientific arguments developed by Kemi are not robust, we would like to highlight the consequences of this proposal. Indeed, if the reprotox cat 1B classification is attributed to the silver ion, this means that silver and other silver compounds will have to be classified as reprotox cat. 1B. The same classification will apply also to the alloys containing silver. The regulatory and economic consequences will be huge for the precious metals industry but also for the downstream sectors using silver in industrial applications (e.g.: photovoltaics, electronics, photography), in jewellery, in silverware and also as investments. Indeed, a substance classified as reprotox cat 1B can be restricted for consumer use as substance and substance in mixture (REACH, articles 68.2 and 133.4). This means that silver will be banned from jewellery, electronics, silverware, bank investments, coinage but also from medical devices (following (2012/0266 (COD))). Moreover, all the biocidal uses as active substance of silver and silver compounds will also be restricted based on BPR (EC N° 528/2012). This would mean that most of the critical uses of silver in the EU could be banned.

The EU remains an important player in silver: the EU represents 6,6% of the silver mine production worldwide and 25% of the silver recycling worldwide. The production of industrial applications and of jewellery in the EU is also significant (12,5 % of the worldwide production). Moreover, there are several applications in the fields of the biocides or connectivity which are under development in the



EU in emerging market like the smart clothing, a market which could multiply from 24M\$ to 849M\$ in 2021 at worldwide level.

The harmonization of the classification and labelling of silver zinc zeolite will be discussed at the RAC meeting in December 2015. We would be very happy to discuss further with you our technical comments but also the downstream consequences of the attribution of the reprotox cat 1B classification to silver ion in preparation of this meeting.

We thank you in advance for the attention that you will bring to this critical issue for the Precious Metals industry and remain available for more information.

Best regards,

France Capon  
European Precious Metals Federation, Secretary General