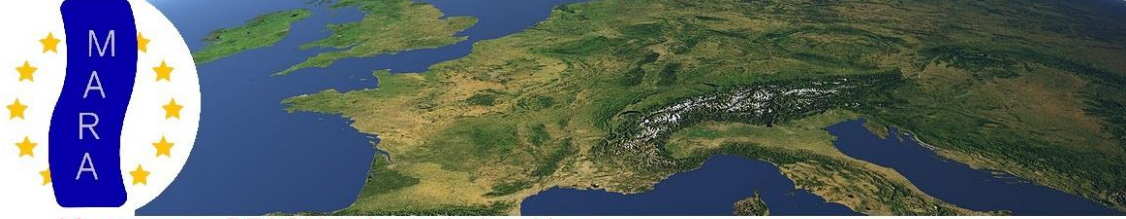
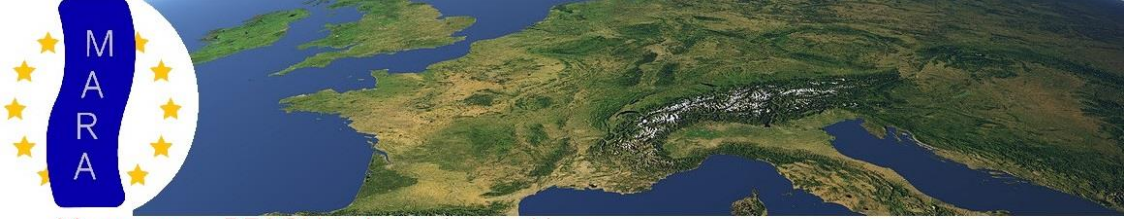
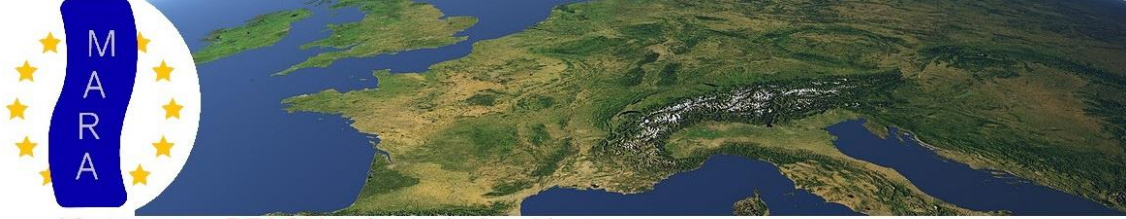


ASSESSMENT OF REGULATORY NEEDS FOR SIMPLE MANGANESE SUBSTANCES
WHERE WE ARE

Webinar February Series

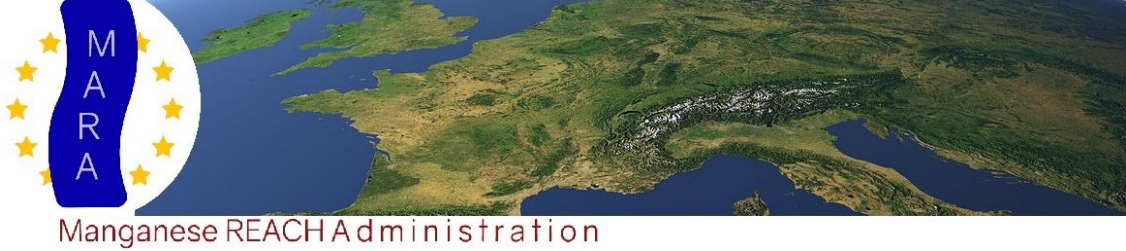


-UNDERSTANDING READACROSS GROUPINGS & DOSSIER STRENGTH/WEAKNESSES
- LEGAL/REGULATORY ASPECTS ON THE ARN
-HIGHLIGHT SOME ARN OUTCOMES
-FINANCE/FINANCIAL MANAGEMENT



READACROSS GROUPINGS DOSSIER STRENGTH & WEAKNESSES IN THE NUTSHELL

GROUPs



MnCl2
MnSO4
Mn(NO3)2

→ Salts, Mn2+; very H2O soluble; very bioavailable

MnCO3
MnO

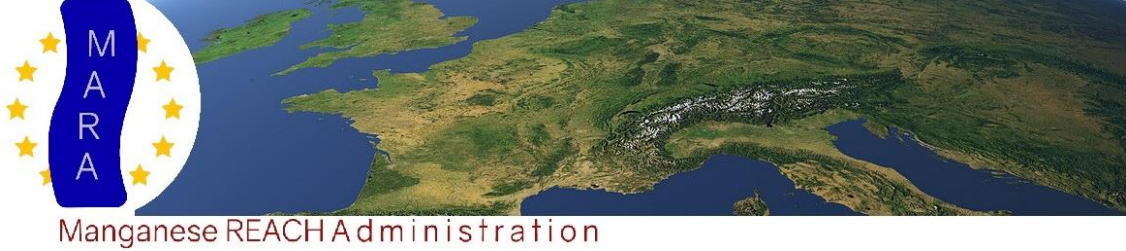
→ Oxides, Mn2+; sparingly H2O soluble; bioavailable

SiMn slag
FeMn slag
Sinter ore

→ UVCB; sparingly H2O soluble; less bioavailable

Components/content	SiMn slag (%w/w) (SOURCE A)	FeMn slag (%w/w) (TARGET SUBSTANCE)	MnCl2/MnSO4 (Mn2+) (SOURCE B)
Silicon dioxide	ca. 31.8 (30-50)	ca. 31 (16-44)	0
Aluminium oxide	ca. 12.49 (7-30)	ca. 11 (0-24)	0
Barium oxide	ca. 1.18 (0-5)	ca. 1.5 (0-5)	0
Calcium oxide	ca. 26.02 (15-40)	ca. 24.5 (11-45)	0
Iron	0	≤0.04 (0-1.55)	0
Manganese	ca. 9.3 (0-13)	ca. 14.6 (7-31.6)	>95%w/w
Manganese oxide	0	ca. 18.9 (10-44)	
Magnesium oxide	ca. 3.72 (3-15)	ca. 3.9 (1-12)	0
Silicon	ca. 4.7 (0-6.6)	0	0

Not in GROUPs

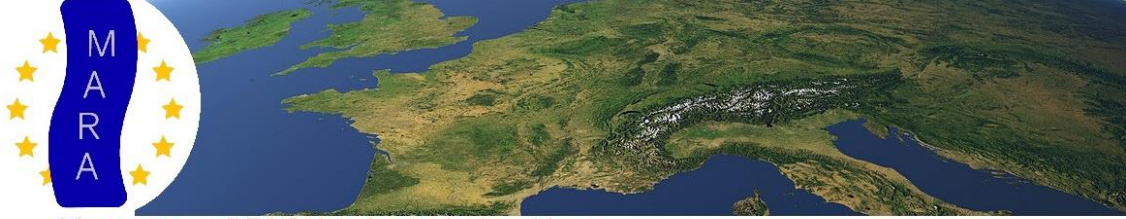


MnO2 → Mn4+; insoluble; not bioavailable

Mn → Mn0; insoluble; partially bioavailable

Mn3O4 → Mn2+, Mn3+; partially soluble; partially bioavailable

MnS → Mn2+; sparingly H2O soluble; less bioavailable

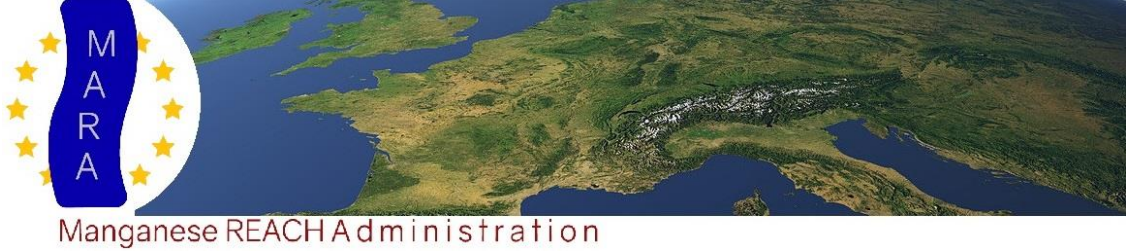


FOCUS ON

SPECIFIC TARGET ORGAN TOXICITY (STOT RE)

REPRODUCTIVE TOXICITY – INCLUDING PRENATAL DEVELOPMENT

Present status of affairs:
leading to possible work



Mn:

STOT: 90 days chronic inhalation exposure study – No STOT however, significant data (epi studies) on alloys do support STOT. (tasks force required to examine components/purity/impurity/exposure levels of the alloys in these studies)

No data on Repro – data on salts was used as worse-case

Salts:

STOT: Already STOT RE 2 – $MnSO_4$ has a harmonised Classification as STOT RE 2 hence this was read across. This needs to be defended as it could become RE 1.

Advocacy could be needed to ensure the authorities maintain the harmonise classification in the absence of any new data

Repro: Significant amount of data conclude - Not Repro

$MnCO_3$ + MnO: No classification;

STOT: No chronic 90 days study- with a valency of Mn^{2+} - this could end up as a STOT RE 2 as per the salts or a 90 days study proposal put in place

Repro data not sufficient – used Salts data as worse-case – if this is acceptable then the STOT should apply. PND rabbit study exist on $MnCO_3$ – No effects

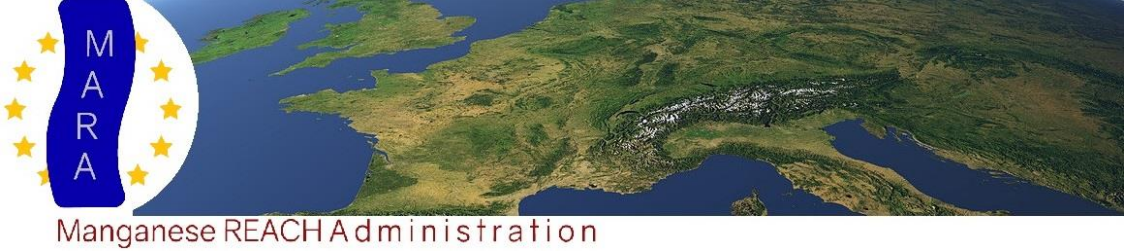
MnO_2:

STOT RE 2 (from literature): This needs to be defended as it could become RE 1. Mn/Neurotox experts required

No repro studies - used Salts data as worse-case – position needs to be defended – Repro experts required

Some status of affairs

leading to possible work



Mn3O4: Multiple valency substance

No STOT (literature is weak/non-existent). – A 90 days study could be requested or proposed

Repro: No Repro study exist – used salts as worse-case – this could be challenged – in which case an EOGRTs could be the only way forward with neurotox endpoint. However, developmental OECD study exist – classified as cat 2 affecting the unborn child

MnS: Lower tonnage band

No STOT classification ;
No Repro classification

Such studies are not in the REACH information requirement for lower tonnage bands – legal arguments/experts will need to be on board.

UVCB's FeMn slags, SiMn slags and Sinter ore:

No STOT: 90 days and TK study exist to OECD and GLP guidelines
Repro data : No EOGRTs/ or Two Gen study exist. However, Cat 2 for developmental tox is application. – PND data on rats (no effects) and and PND study on rabbits = effects:

However, the issue seems to be on the presence of SiO2 in professional use so to resolve this issue we plan to:

Characterisation by particle sizes – massives vs powder.
– if massives then there is no possibility of lung effect except for lung overload

Conduct some bioaccessibility studies on aveoli fluid to under any components leaching

XRD will show SiO2 as amorphous and not crystaline – characterisation of the slags

Understanding the exposure scenarios of our downstream user – cement/hardcore/ construction industry

Components/content	SiMn slag (%w/w) (SOURCE A)	FeMn slag (%w/w) (TARGET SUBSTANCE)	MnCl2/MnSO4 (Mn2+) (SOURCE B)
Silicon dioxide	ca. 31.8 (30-50)	ca. 31 (16-44)	0
Aluminium oxide	ca. 12.49 (7-30)	ca. 11 (0-24)	0
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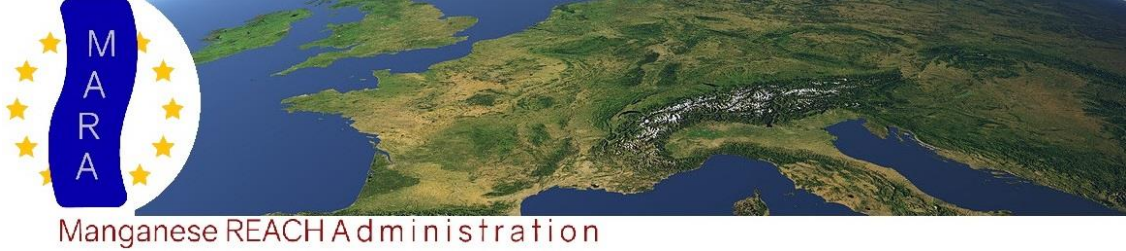
Projected workload- In summary



Mn: lit search and evaluation on STOT effects from alloys – Justify classification or lack of it and put in an EOGRT study testing proposal (ca. 1million euros)

Salts ($MnCl_2$/$MnSO_4$/$Mn(NO_3)_2$): Advocacy to maintain classification

$MnCO_3$ and MnO: Engage Scientific tasks force to ensure STOT classification is not readacross or put in a 90 days chronic exposure testing proposal (ca. €300K)

MnO_2: Engage Scientific tasks force to ensure STOT RE 2 classification is maintained + advocacy

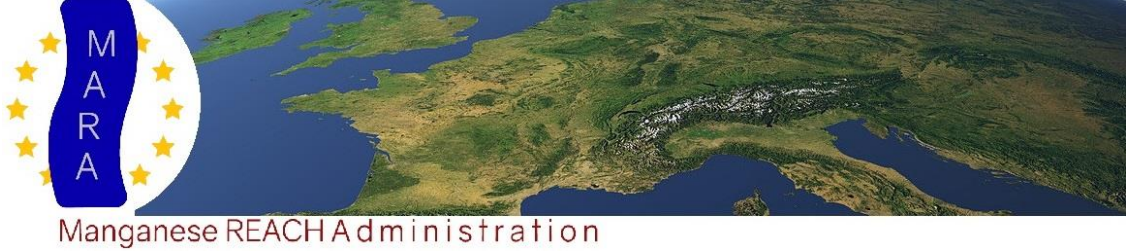
Mn_3O_4: 90 days chronic exposure testing proposal (ca. €300K) + advocacy to use Repro study from salts

MnS: Legal justification for lack of regulatory need based on tonnage band

UVCB's FeMn slags, SiMn slags and Sinter ore: (ca. €100K)
Characterisation by particle sizes – massives vs powder.
Conduct some bioaccessibility studies on aveoli and stomach fluid
XRD will show SiO_2 as amorphous and not crystaline – characterisation of the slags

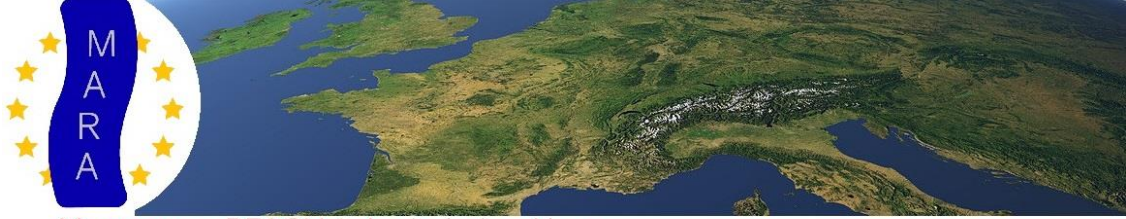
Understanding the exposure scenarios of our downstream user – cement/hardcore/ construction industry

To conclude

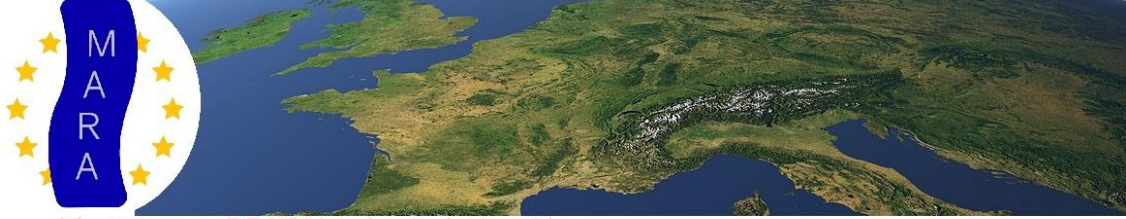


- Keep a keen eye on your REACH IT/ Monitor ECHA news
- Industry must work together – CLH is not tonnage band specific
- Certain classifications can affect business and lead to restriction
- The first outcome of the ARN could be CCH – this could lead to testing projected at ca. €1.7 – 2 million
- The main risk is a blanket STOT classification (all substances)
- The second risk is those substances already classified as STOT RE 2 to become STOT RE 1 – a higher category means the substances can enter the list of SVHC
- Data on Repro is strong – but scientific argument to use available data across all substances is needed
- Some degree of advocacy is required to maintain the present self and harmonised classifications status

ALL dossiers will need to be updated accordingly – as the authorities draw conclusions based on data from our dossiers

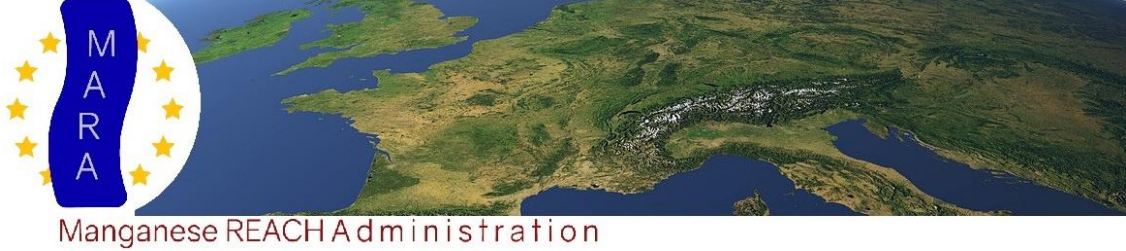


THANK YOU!
END OF SESSION 1



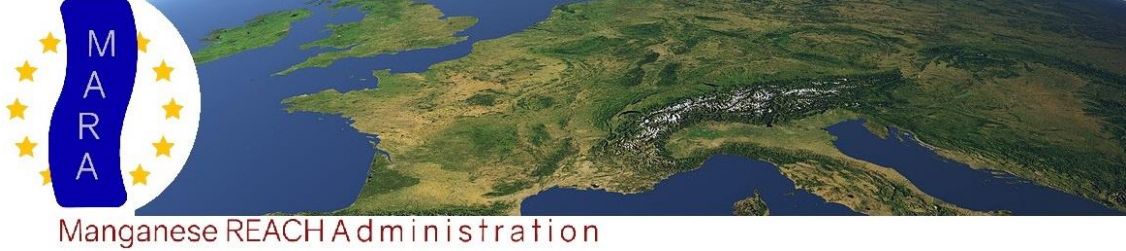
ARN
POSSIBLE OUTCOMES
SESSION 3

C&L status according to ARN vs MARA's



Substance name	EC / List no	CAS no	Authority	Concern	Status	Follow-up	Date of	MARA's C&L
Manganese	231-105-1	7439-96-5	Sweden	STOT RE Toxic for reproduction	Under development	No suggestion yet		None
Manganese carbonate	209-942-9	598-62-9	Sweden	STOT RE Toxic for reproduction	Under development	No suggestion yet		None
Manganese dichloride	231-869-6	7773-01-5	Sweden	STOT RE Toxic for reproduction	Under development	No suggestion yet		STOT RE 2
Manganese dinitrate	233-828-8	10377-66-9	Sweden	STOT RE Toxic for reproduction	Under development	No suggestion yet		STOT RE 2
Manganese dioxide	215-202-6	1313-13-9	Sweden	STOT RE Toxic for reproduction	Under development	No suggestion yet		STOT RE 2
Manganese oxide	215-695-8	1344-43-0	Sweden	STOT RE Toxic for reproduction	Under development	No suggestion yet		None
Manganese sulphate	232-089-9	7785-87-7	Sweden	STOT RE Toxic for reproduction	Under development	No suggestion yet		STOT RE 2
Manganese sulphide	242-599-3	18820-29-6	Sweden	STOT RE Toxic for reproduction	Under development	No suggestion yet		None
Dimanganese trioxide Process related name: Manganese (III) oxide	215-264-4	1317-34-6	Sweden	STOT RE Toxic for reproduction	Under development	No suggestion yet		Not in MARA's portfolio
Trimanganese tetraoxide IUPAC name: manganese tetraoxide	215-266-5	1317-35-7	Sweden	STOT RE Toxic for reproduction	Under development	No suggestion yet		Repro Cat 2 (Dev)

Different ARN conclusions exist – 1) Lanthanum



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ASSESSMENT OF REGULATORY NEEDS

2 Conclusions and proposed actions

The conclusions and actions proposed in the table below are based mainly on the REACH and CLP information available at the time of the assessment by ECHA. The conclusions are preliminary suggestions from a screening-level assessment done by ECHA with the aim to propose the next steps for further work (e.g., strengthening of the hazard conclusions, clarification of the uses and/or potential for exposure). The main source of information is the registration dossiers. Relevant public assessments may also be considered. When new information (e.g., on hazards through evaluation processes, or on uses) will become available, the document may be updated, and conclusions and actions revisited.

Table 1: Conclusions and proposed actions

EC/List no	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
209-599-5 213-034-8 215-200-5 231-099-0 233-237-5 233-238-0 237-252-8 238-510-2 600-351-5	Known or potential hazard for reproductive toxicity for all Known or potential hazard for skin sensitisation for EC 233-237-5 Inconclusive hazard for ED for all	Known or potential hazard for aquatic toxicity for all	Mainly industrial uses with limited potential for exposure and release. Two substances EC 215-200-5 and 237-252-8 with high exposure potential from widespread professional uses as polishing powders, non metal and metal (EC 215-200-5 only) surface treatment are reported, EC 215-200-5 also professional and consumer uses in coatings and paints.	**First step:** **CCH** for EC 237-252-8, 233-238-0, 209-599-5, 215-200-5, 238-510-2, 233-237-5 **Potential next steps (if hazard confirmed after data generation):** CLH **Potential last action:** **Restriction for professional uses, OEL for industrial uses (under REACH or OSH)** Justification: Harmonised classification as Repr 1B would lead to generic restriction of the substance(s) in consumer mixtures by means of restriction entry 30 .

Different ARN conclusions exist – 2) Chronium

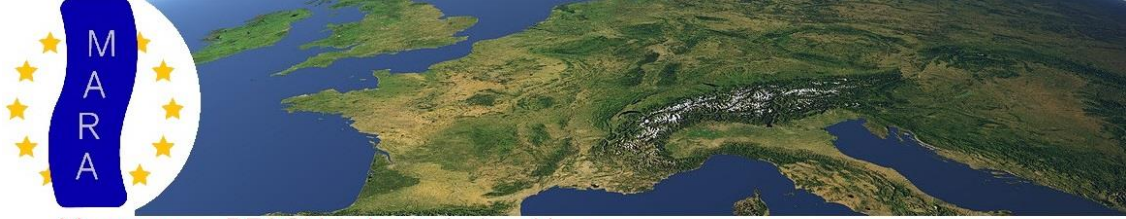

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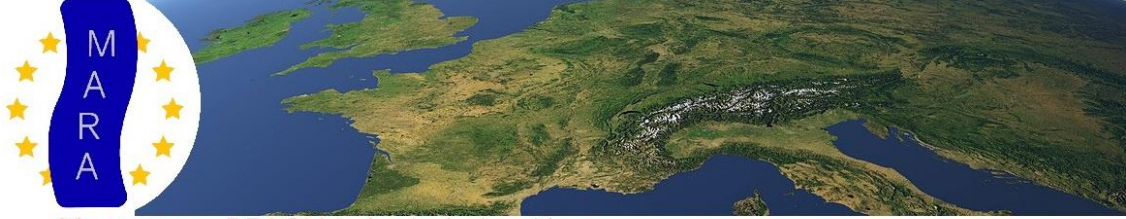
Table 1: Conclusions and proposed actions

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
All group members	Inconclusive hazard for reproductive toxicity for ED For all substances Known or potential hazard for skin sensitisation For all subgroup 1 substances No hazard or unlikely hazard for carcinogenicity, for mutagenicity, for STOT RE For all substances	Potential hazard for aquatic toxicity For all substances except EC 231-157-5, 234-361-2, 234-499-3, 234-576-1, 235-002-2, 235-790-8, and 915-035-5 No hazard or unlikely hazard for PBT/vPvB, for PMT For all substances Inconclusive hazard for ED For all substances	For most substances (except EC 234-361-2, 234-499-3, 244-256-3, 254-447-3 and 944-862-4) IND, PROF uses where potential for exposure is likely (metal and/or non-metal surface treatment, coatings and paints, thinners, paint removes, adhesive and sealants)	**First step** CCH for EC 233-038-3 **Potential last action:** Currently not possible to assess the regulatory needs Justification: Inconclusive hazard for reproductive toxicity and ED

Different ARN conclusions exist – 3) slags



Other slag substances 266-968-3 Slags, copper smelting 273-732-3 Slags, phosphorus-manufg. 282-217-2 Slags, ferromolybdenum-manufg., silicothermic 310-060-2 Slags, elec. furnace smelting, iron silicate	Not assessed. For further information see Annex 1.	Widespread professional and consumer use in construction materials, fillers for earthwork, fertilisers, water treatment and abrasive agents. Industrial uses in construction materials and fillers for earthwork and as intermediate. Potential for exposure for workers and consumers and release to environment.	**Currently no need for EU RRM** Justification: Overall, no or unlikely hazard that would lead to concern for the reported uses.

- Best case

Dr Doreen McGough; Executive Director of the Mn Consortium with over 20 years' work experience in the industry, 14 of which have been spent dealing solely with manganese.

Thank you! Any questions?