

MARA - EU regulatory / legal updates
Session 2

Webinar series -
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MARA - EU regulatory / legal updates

- A. Grouping
- B. Specific substances & Restriction process
- C. MARA strategy
- D. Funding

A. Grouping

Broader EU regulatory context remains unaltered:

- ARN for simple manganese compounds – ECHA 7 December 2021
 - 29 manganese compounds grouped based on similarity and presence of manganese.
 - ECHA recommended **CLP classification** (Cat 1B reprotoxicity and STOT RE neurotoxicity), and
 - **REACH restriction** for manganese compounds sub-grouped as (i) simple inorganic salts, oxides and manganese metal; and (ii) permanganates
- Restriction Roadmap under CSS – EU Commission Staff Working Document 25 April 2022
 - Prioritizes 15 simple manganese compounds for **REACH restriction** on the basis of the same hazards under Pool 2 – “Potential restrictions”

B. Specific substances

Specific context has evolved :

- **Sweden** registered its intention to initiate ARNs on several manganese compounds
 - no specific timeline (from 10 months to several years) as ARNs are voluntary and there is no legal basis under REACH (different from CoRAP)
 - no automatic trigger of regulatory actions (yet)
 - BUT, the fact that Sweden has decided to conduct ARNs on manganese substances shows **increasing regulatory pressure for regulatory measures at EU level**
 - → → **Mara needs to act !**

B. Specific substances

- We have checked each of Mara's portfolio components to see if there was any development

Substance name	SIEF nominated Lead registrant	EU developments
Manganese 231-105-1 7439-96-5	Exponent OR for Assore	Sweden has registered its intention to conduct an ARN on 8 Dec 2023 for the following concerns: <ol style="list-style-type: none"> 1. STOT RE 2. Toxic for reproduction <p>At this stage, it is <u>not yet known</u> what EU measures will be suggested</p>
Manganese oxide 215-695-8 1344-43-0	Vibrantz	Sweden has registered its intention to conduct an ARN on 8 Dec 2023 for the following concerns: <ol style="list-style-type: none"> 1. STOT RE 2. Toxic for reproduction <p>At this stage, it is <u>not yet known</u> what EU measures will be suggested</p>
Manganese dioxide 215-202-6 1313-13-9	Tosoh Hellas A.I.C.	Sweden has registered its intention to conduct an ARN on 8 Dec 2023 for the following concerns: <ol style="list-style-type: none"> 1. STOT RE 2. Toxic for reproduction <p>At this stage, it is <u>not yet known</u> what EU measures will be suggested</p>
Trimanganese tetraoxide 215-266-5 1317-35-7	Vibrantz	Sweden has registered its intention to conduct an ARN on 8 Dec 2023 for the following concerns: <ol style="list-style-type: none"> 1. STOT RE 2. Toxic for reproduction <p>At this stage, it is <u>not yet known</u> what EU measures will be suggested</p>

B. Specific substances

Substance name	SIEF nominated Lead registrant	EU developments
Manganese carbonate 209-942-9 598-62-9	Vibrantz	Sweden has registered its intention to conduct an ARN on 8 Dec 2023 for the following concerns: <ol style="list-style-type: none"> 1. STOT RE 2. Toxic for reproduction <p>At this stage, it is not yet known what EU measures will be suggested</p>
Manganese sulphate 232-089-9 7785-87-7	Vibrantz	Sweden has registered its intention to conduct an ARN on 8 Dec 2023 for the following concerns: <ol style="list-style-type: none"> 1. STOT RE 2. Toxic for reproduction <p>At this stage, it is not yet known what EU measures will be suggested</p>
Manganese dinitrate 233-828-8 10377-66-9	Vibrantz	Sweden has registered its intention to conduct an ARN on 8 Dec 2023 for the following concerns: <ol style="list-style-type: none"> 1. STOT RE 2. Toxic for reproduction <p>At this stage, it is not yet known what EU measures will be suggested</p>
Slags, FeMn manufacturing 273-728-1 69012-28-8	XEAL	ECHA's ARN of 29 Nov 2023 (still under development) suggests restriction of professional uses . There is no explicit reference to the concern (only mention that these two compounds are self-classified as Repr. 2) and with the following justification:
Slags, SiMn manufacturing 273-733-9 69012-33-5	XEAL	"The reported professional uses are widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses"

B. Specific substances

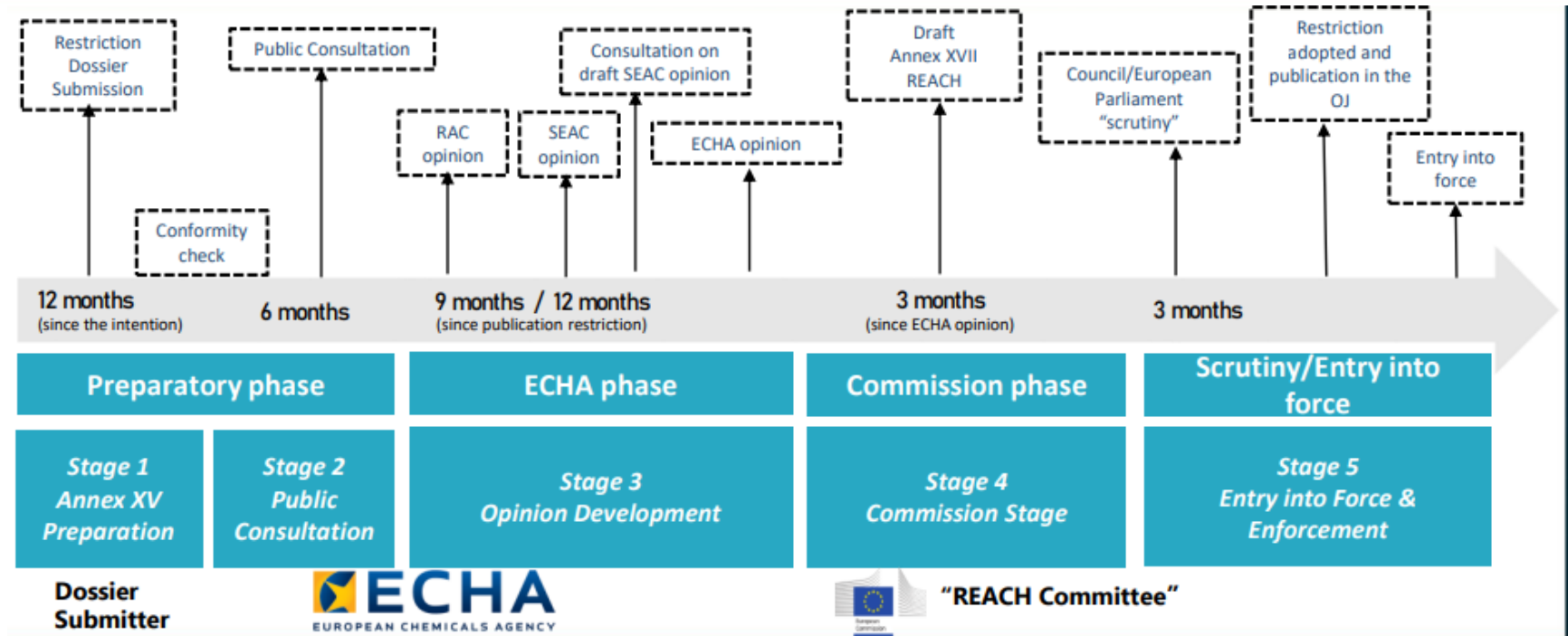
Substance name	SIEF nominated Lead registrant	EU developments
Manganese ores, reduced 273-748-0 69012-49-3	Ferroglobe Manganese France	N/A
Manganese dichloride 231-869-6 7773-01-5	Vibrantz	Sweden has registered its intention to conduct an ARN on 8 Dec 2023 for the following concerns: <ol style="list-style-type: none"> 1. STOT RE 2. Toxic for reproduction <p>At this stage, it is <u>not yet known</u> what EU measures will be suggested</p>
Manganese sulphide 242-599-3 18820-29-6	Höganäs AB	Sweden has registered its intention to conduct an ARN on 8 Dec 2023 for the following concerns: <ol style="list-style-type: none"> 1. STOT RE 2. Toxic for reproduction <p>At this stage, it is <u>not yet known</u> what EU measures will be suggested</p>
Manganese ores, reduced 273-748-0 69012-49-3	Ferroglobe Manganese France	N/A

B. Specific substances

For other manganese compounds, which are not on MARA's portfolio, ARNs are also being developed :

- Resin acids and Rosin acids, manganese salts 232-716-6 9008-34-8
- Manganese neodecanoate 248-374-6 27253-32-3
- Calcium-Iron-Silicium-Magnesium-Manganese-Aluminium oxide equivalent 932-275-6
- Calcium-Silicium-Magnesium-Aluminium-Iron-Manganese oxide equivalent 932-476-9
- The Permanganates – Group II

B. Restriction process



C. MARA strategy

- Grouping approach
 - Securing a fair regulatory review and defence of Manganese Compounds through scientific / advocacy / legal initiatives
 - Raise inadequacy of wide grouping where unsupported
- Specific substances – avoid worse CLP classification & Restriction
 - Address substance specific technical aspects / read-across issues
 - Position papers, legal notes, meetings with authorities etc.
 - Advocacy strategy → approach Sweden and other Member States

D. Funding approach

- Funding - escrow account
 - Yearly budget set based on anticipated actions
 - Cash calls to all SIEF EU REACH Registrants
 - Payments made on escrow account administered by Fieldfisher
 - When invoices are received (e.g. third parties consultants, labs etc.) these are reviewed/approved by MARA and paid by Fieldfisher from escrow account
 - Transparent and efficient management of account

Thank you!



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