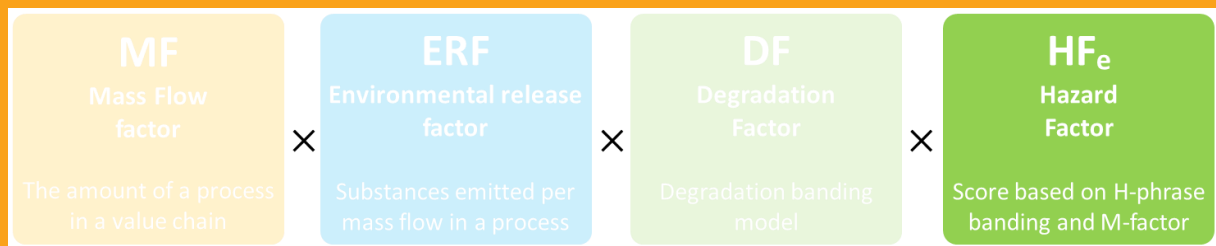


# Key Feature 1: ProScaleE Hazard scoring model

Pearl Nemeth, Anthesis, 31/05/2024





# Content

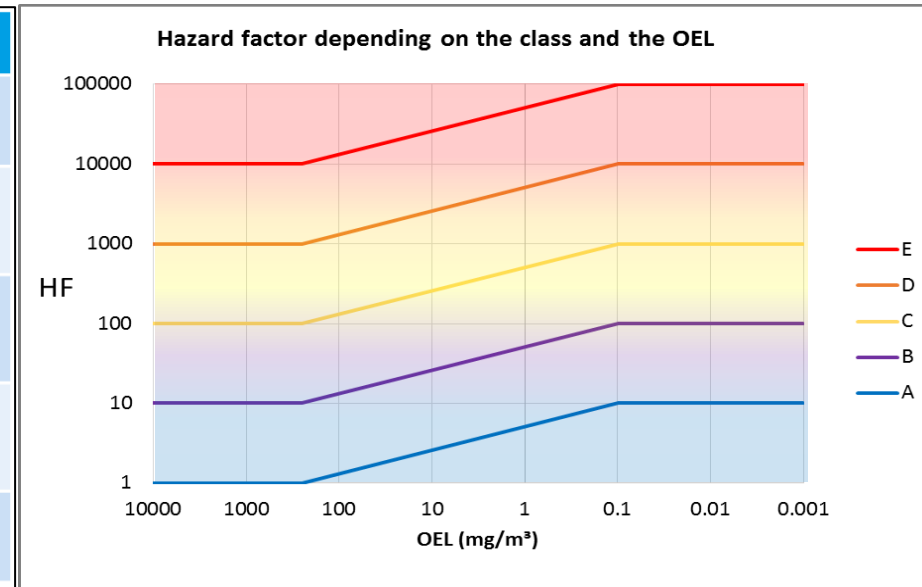
- Starting points and aspirations
- Challenges
- Key results



# Starting points and aspirations #1

- ProScale human health hazard banding

ProScale Hazard class	H-phrases according to GHS/CLP, grouped by exposure route
<b>E</b> 10 000 - 100 000 (highest hazard)	All routes : H340, H350, H360, H362
<b>D</b> 1000 - 10 000	Dermal : H310 Inhalation : H330, H334, EUH032 Oral : H300, All routes : H341, H351, H361, H372
<b>C</b> 100 - 1000	Dermal : H311, H314, H317, H318, EUH070 Inhalation : H331, EUH029, EUH031, EUH071 Oral : H301, H304 All routes : H370, H373
<b>B</b> 10 - 100	Dermal : H312, H315, H319, Inhalation : H332, H335 Oral : H302 All routes : H371
<b>A</b> 1 - 10 (lowest hazard)	Dermal : H313, H316, H320, EUH066 Inhalation : H333, H336 Oral : H303, H305,



# Starting points and aspirations #2

- ProScale human health hazard banding
- GHS/CLP + new hazard classes

Environmental Hazard categories	Hazard phrases
Acute aquatic environmental hazard	H400
Chronic aquatic environmental hazard category 1-4	H410, H411, H412, H413
ED ENV (Endocrine disruptors for the environment) category 1 & 2	EUH430 and EUH431
PBT (persistent, bioaccumulative, toxic), vPvB (very persistent, very bioaccumulative)	EUH440 and EUH441
PMT (persistent, mobile, toxic), vPvM (very persistent, very mobile)	EUH450 and EUH451

## 'M-factor':

- It means a multiplying factor.
- It is applied to the concentration of a substance classified as hazardous to the aquatic environment acute category 1 or chronic category 1, and
- In RA it is used to derive by the summation method the classification of a mixture in which the substance is present;
- In ProScaleE used as a Hazard potency modifier on individual substances

EC50	M-factor
$0.1 < L(E)C50 \leq 1$	1
$0.01 < L(E)C50 \leq 0.1$	10
$0.001 < L(E)C50 \leq 0.01$	100
$0.0001 < L(E)C50 \leq 0.001$	1 000
$0.00001 < L(E)C50 \leq 0.0001$	10 000
...	...

# Starting points and aspirations #3


- ProScale human health hazard banding
- GHS/CLP + new hazard classes
- SVHC (substances of very high concern) approach and the broader Safe and Sustainable by Design hazard banding

Table 3. List of aspects and indicators (hazard properties) relevant for Step 1.

Group definition	Human health hazards	Environmental hazards	Physical hazards
Includes the <u>most harmful substances</u> (according to CSS (EC, 2020a)), including the <u>substances of very high concern</u> (SVHC) according to REACH Art. 57(a-f) <sup>13,14</sup> (EU, 2006). These hazard properties will form <u>Criterion S1</u> .	<ul style="list-style-type: none"> <li>• Carcinogenicity Cat. 1A and 1B</li> <li>• Germ cell mutagenicity Cat. 1A and 1B</li> <li>• Reproductive / developmental toxicity Cat. 1A and 1B</li> <li>• Endocrine disruption Cat. 1 (human health)</li> <li>• Respiratory sensitisation Cat. 1</li> <li>• Specific target organ toxicity - repeated exposure (STOT-RE) Cat. 1, including immunotoxicity and neurotoxicity</li> </ul>	<p style="text-align: center;"><b>Not-SSbD</b></p> <ul style="list-style-type: none"> <li>• Persistent, bioaccumulative and toxic / very persistent and very bioaccumulative (PBT/vPvB)</li> <li>• Persistent, mobile and toxic / very persistent and mobile (PMT/vPvM)</li> <li>• Endocrine disruption Cat. 1 (environment)</li> </ul>	
Includes <u>hazardous substances with chronic effect</u> , which are part of the <u>substances of concern</u> , described in CSS (EC, 2020a) and are not included already in Criterion S1. These hazard properties will form <u>Criterion S2</u> .	<ul style="list-style-type: none"> <li>• Skin sensitisation Cat. 1</li> <li>• Carcinogenicity Cat. 2</li> <li>• Germ cell mutagenicity Cat. 2</li> <li>• Reproductive / developmental toxicity Cat. 2</li> <li>• Specific target organ toxicity - repeated exposure (STOT-RE) Cat. 2</li> <li>• Specific target organ toxicity - single exposure (STOT-SE) Cat. 1 and 2</li> <li>• Endocrine disruption Cat. 2 (human health)</li> </ul>	<p style="text-align: center;"><b>Safety Level 1</b></p> <ul style="list-style-type: none"> <li>• Hazardous for the ozone layer</li> <li>• Chronic environmental toxicity (chronic aquatic toxicity)</li> <li>• Endocrine disruption Cat. 2 (environment)</li> </ul>	
Includes the <u>other hazard classes</u> not part already in Criteria S1 and S2. These hazard properties will form <u>Criterion S3</u> .	<ul style="list-style-type: none"> <li>• Acute toxicity</li> <li>• Skin corrosion</li> <li>• Skin irritation</li> <li>• Serious eye damage/eye irritation</li> <li>• Aspiration hazard (Cat. 1)</li> <li>• Specific target organ toxicity - single exposure (STOT-SE) Cat. 3</li> </ul>	<p style="text-align: center;"><b>Safety Level 2</b></p> <ul style="list-style-type: none"> <li>• Acute environmental toxicity (acute aquatic toxicity)</li> </ul>	<ul style="list-style-type: none"> <li>• Explosives</li> <li>• Flammable gases, liquids and solids</li> <li>• Aerosols</li> <li>• Oxidising gases, liquids, solids</li> <li>• Gases under pressure</li> <li>• Self-reactive</li> <li>• Pyrophoric liquids, solid</li> <li>• Self-heating</li> <li>• In contact with water emits flammable gas</li> <li>• Organic peroxides</li> <li>• Corrosivity</li> <li>• Desensitised explosives</li> </ul>



# Challenges

- Subjective aspect of scoring acute and chronic hazards and persistence chemicals
  - Overlap between persistency and environmental fate
  - Whether to have a separate scaling for potency based on EC50 values and M-factors
  - Data Lacking (especially in new hazard categories vs. acute and chronic aquatic toxicity)
- 

# Key results

- Similar banding to ProScale HH
- SVHC/SSbD approach applied with whereby highest score given to chemicals with no safe threshold and highest potency

## Hazard factor HF: H-phrases and M factors

ProScale hazard class	CLP hazard categories	H-score
E (10 000 – 100 000)	PBT/vPvB	100 000
	PMT/vPvM	100 000
	ED, env cat 1	100 000
	Chronic aquatic toxicity 1 (H410), M-factor ≥ 10 000	100 000
	Chronic aquatic toxicity 1 (H410), M-factor = 1000	30 000
D (1000 – 10 000)	ED, env cat 2	10 000
	Chronic aquatic toxicity 1 (H410), M-factor = 100	10 000
	Acute aquatic toxicity (H400), M-factor ≥ 10.000	10 000
	Chronic aquatic toxicity 1 (H410), M-factor = 10	3000
	Chronic aquatic toxicity 1 (H410), M-factor = 1	1000
	Acute aquatic toxicity (H400), M-factor = 1000	3000
C (100 – 1000)	Chronic aquatic toxicity 2 (H411)	1000
	Acute aquatic toxicity (H400), M-factor = 100	1000
	Acute aquatic toxicity (H400), M-factor = 10	300
B (10 – 100)	Chronic aquatic toxicity 3 (H412)	100
	Acute aquatic toxicity (H400), M-factor = 1	100
A (1 - 10)	Chronic aquatic toxicity 4 (H413)	10
No hazard	No class ("regarded as safe")	-

Not-SSbD

Safety Level 1

Safety Level 2

Safety Level 3



**Thank you !**



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