



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Possible SVHCs

Where exposure data make the
difference



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Exposure in REACH

- ✓ For the risk management of chemicals in the supply chain
- ✓ For enabling authorities identifying substances which may require regulatory actions and defining the most appropriate regulatory instrument

REACH requires the registrants to provide exposure info in the CSR

- readily understandable
- relevant
- well documented, and
- easily identifiable



An example to
illustrate the importance of
exposure within the framework of the
SVHC Roadmap



UVCB with impurity X

Substance: UVCB containing impurity

Tonnage band: 1.000 – 10.000 t/a

Type of use:

- Wide dispersive
- Industrial and professional use

Concern: Repro. 1B due to impurity X

- Very potent reproductive toxicant
- Typical occurrence: 0.042% (w/w)
- Concentration range: 0.0 – 1.0% (w/w)
- Specific concentration limit: 0.3% (w/w)



Preliminary RMOA

- ✓ Conclusion from manual screening: Possible SVHC
- ✓ Concern for those cases where X concentration >0.3 % (w/w)
- ✓ Concern for workers during manufacturing and formulation
- ✓ Concern for environmental exposure

Exposure data too limited to exclude concerns:

→ RMOA based on reasonable worst case assumptions

Exposure data too limited to identify specific risks:

→ Targeted restriction under REACH is no option

Hence authorization is suggested



Where exposure data make the difference

The NL-CA consulted the registrant.

The registrant cleared issues related to the impurity X content in the UVCB and workers and environmental exposure:

- Impurity X content at all times < 0.3% (w/w)
- UVCB significantly diluted during the life cycle, hence also the concentration of impurity X,
- UVCB is handled mostly under high temperature, which requires workers to use PPE due to other harmful properties, and
- Concentration of impurity X in the end product is very low, and additionally impurity X is bound into matrix, which prevents emissions into the environment.



Final RMOA

- Concern no longer substantiated
- No further risk management options necessary for this substance

The registrant has to update the dossier as to reflect the information communicated to the NL-CA:

- ✓ that the typical concentration of *X* is *at all times* $< 0.3\%$, and
- ✓ to clarify workers and environmental exposure

Follow-up actions necessary to confirm that the registrant has indeed updated the dossier! **In case the dossier is not updated, RMOA will be revisited.**



Concluding thoughts

Hazard is the leading prioritization criterion for the SVHC Roadmap in the absence of good quality information on exposure, often leading to the authorization route as most appropriate regulatory option!

- substances with no or low risk may get prioritized
- inefficient use of public resources
- industry confronted with regulatory pressure



Concluding thoughts

Registrants beware

- authorities take your registration dossiers at face value
- the registration dossier is the basis for the RMOA. The information in there is the only one to be taken into account.

Good quality exposure data in the CSR is a REACH obligation in the interest of the industry because it is fundamental to good regulation!