NORMAN activities on prioritisation: Outlook, what's next

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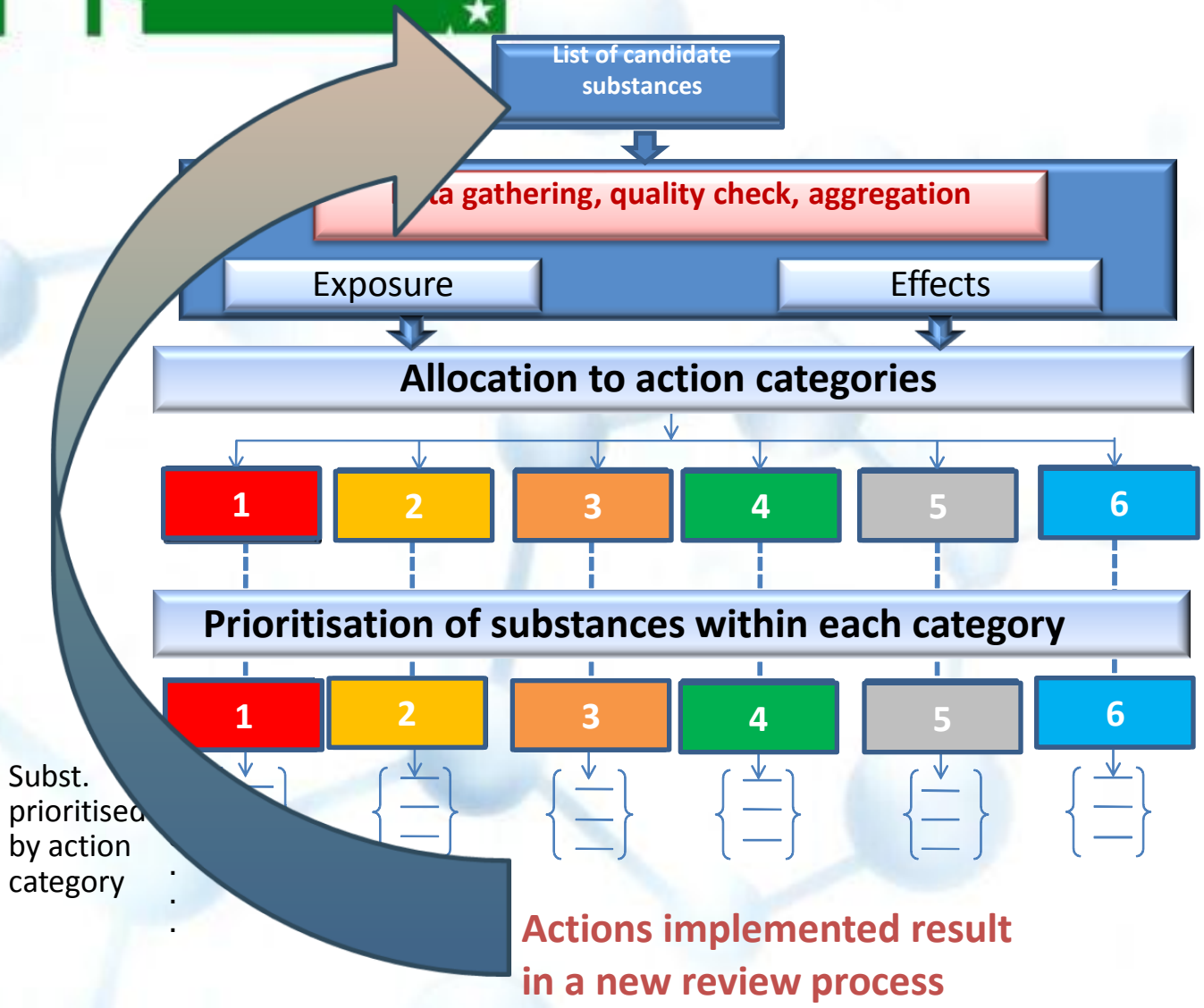
The overall approach



1. Categorisation – to allocate substances to **action categories**

2. Prioritisation – to define priorities within each action category

What's next: improvement of current prioritisation scheme

- **New candidate substances**
  - Revision of the current list of emerging substances, taking into account input from:
    a) non-target screening,
    b) EDA studies
    c) etc…
- Exposure index:
  - Inclusion of an exposure index based on production / usage (i.e. tonnages) and use pattern to allow for improved prioritisation of compounds never monitored but expected to be present in the aquatic compartment

What's next: improvement of current prioritisation scheme

- **EMPODAT Effect data module and lowest PNEC derivation**
  - Improved metadata and criteria for assessment of reliability and relevance of tests, applying the CRED system (Criteria for Reporting and Evaluating Ecotoxicity Data, by *Agestrand et al. 2011*)
  - Implementation of a link between ChemProp and EMPODAT for chemical and (eco)toxicological profiling, using QSAR predictions to derive provisional PNEC (P-PNEC)

What's next: improvement of current prioritisation scheme

- **Improved risk assessment**
  - Going beyond PEC/PNEC ratios for individual substances
  - Identification of mixture toxicity drivers
  - Using field-based MOA-specific bioassays to identify relevant compound classes

Thank you for your attention

Leaders of the activity	
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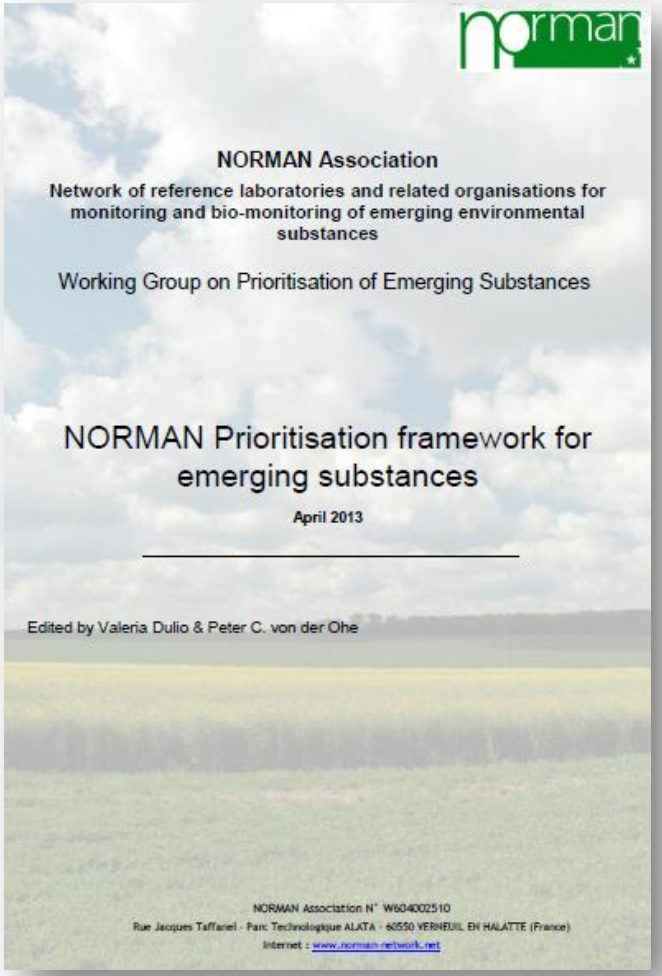


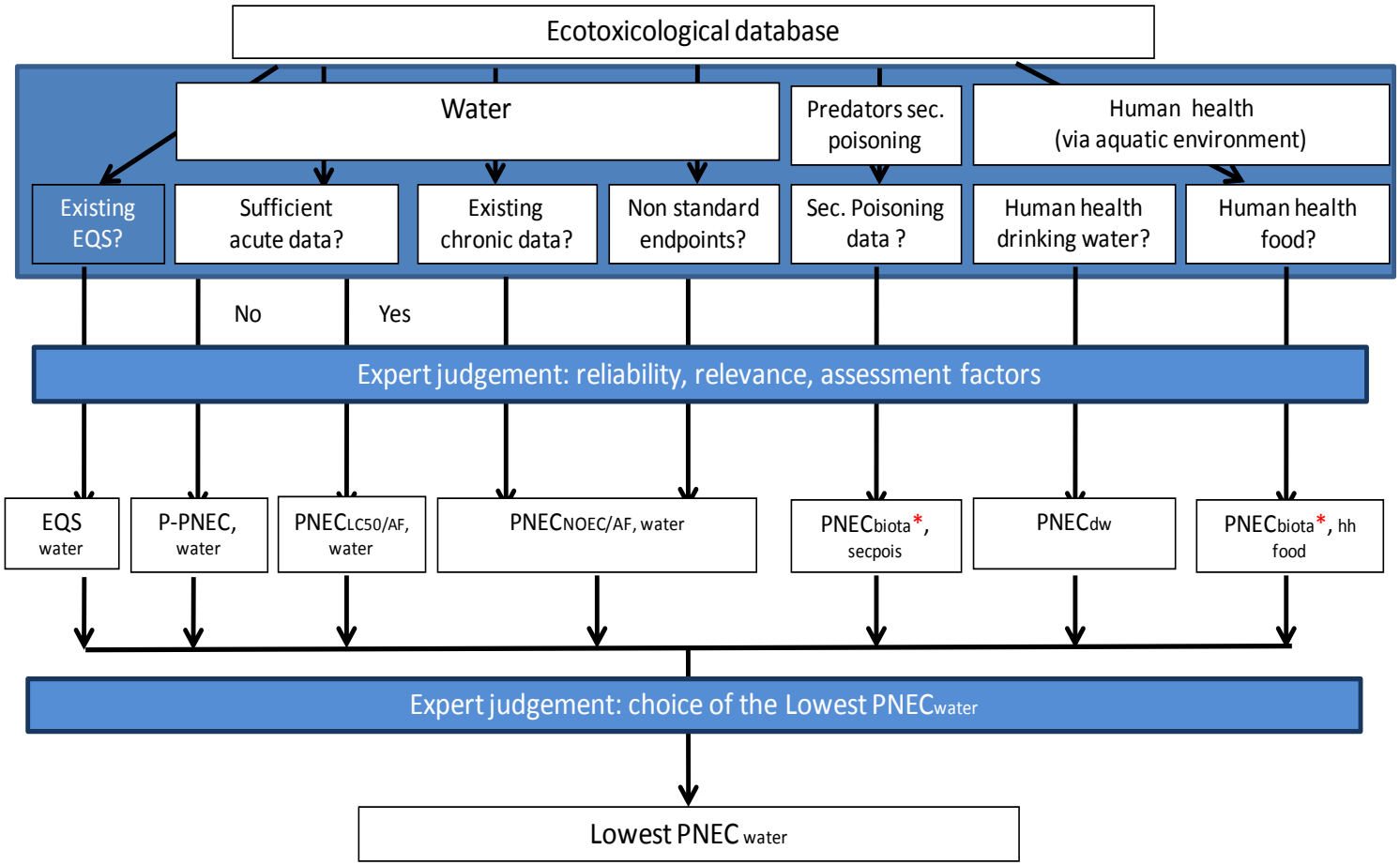
What's next: improvement of current prioritisation scheme

- **Substance Factsheets**
  - Physico-chemical data from databases and QSAR
  - Overview of quality-assessed ecotoxicological ´raw-data´, including the key study
  - Summarising the exposure data
  - Prioritisation indicators and scores
  - Current risk assessment status and priority

➔All you want to know in one place!

- available on the NORMAN website -

Definition: Lowest PNEC (water)
(ref. NORMAN Framework – Section 5.2.3.1)



* back-calculated « $PNEC_{water\ sec\ pois}$ » and « $PNEC_{water,\ hh\ food}$ » expressed in µg/L

Lowest effect threshold among EQS, $PNEC_{NOEC/AF}$, $PNEC_{LC50/AF}$, P–PNEC, $PNEC_{biota\ sec\ pois}$, $PNEC_{biota\ hh\ food}$

NORMAN Prioritisation criteria

Exposure relevance:

- N° of countries/sites with analyses > LOQ, frequency of quantification
- Use pattern

(Eco)toxicological relevance / Hazardous properties :

- PBT, vPvB citeria
- CMR properties
- Endocrine disruption potential
- Novel end points (behavioural effects)

Risk indicators:

- Frequency of exceedence of the PNEC (spatial distribution of impact)
- Extent of exceedance of the PNEC (intensity of impact)

PBT, vPvB criteria (based on Annex XIII REACh)

Persistence (P):

- T1/2: *Kühne R, 2007. Estimation of compartmental half-lives of org. comp. - structural similarity versus EPI-Suite. QSAR Comb. Sci. 26: 542-549*

Bioccumulation (B):

- *BCF (B): Experimental data when available + UFZ Models*

Toxicity (T):

- *T+: Lowest PNEC < 0.01 µg/L*
- *T: Lowest PNEC < 0.1 µg/L*

Existing PBT / vPvB classifications:

- International PBT/POP Lists

Final PBT score: value between 0 and 1

[SUM (P + B + T) + PBT / vPvB] / 4

CMR effects (Human health toxicity)

- EU Regulation on Classification, Labelling and Packaging (CLP, EC 1272/2008)
- IARC Report on carcinogens

Final CMR score: value between 0 and 1

CMR, category 1 : 1
CMR, category 2 : 0.75
CMR, category 3 : 0.5
Under examination: 0.5
Not examined : 0.25
Examined and classified as not CMR: 0

Endocrine disruption effects

- Reviews on EDs by the EU Commission: (EU Commission 2007)
- “SIN List” (Substitute It Now!) (Chem. Sec – SIN List 2.0)
- IEH Report on Chemicals purported to be endocrine disrupters(IEH Report, 2005)

Final ED score: value between 0 and 1

Proven ED effect : 1

Suspect ED effect: 0.5

Not examined: 0.25

Examined and classified as not ED: 0

Risk indicators

To address the intensity of impact:

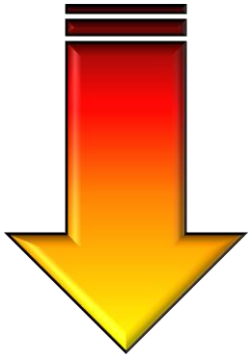
- *Extent of Exceedance = MEC95 / Lowest PNEC*

Where,

- *MEC95 (95th percentile of the max conc. at each site)*
- *Lowest PNEC*
- *Equivalent to PEC/PNEC*

Score for „Exceedance of environmental threshold“

MEC95/lowest PNEC <1 = 0
10≥ MEC95/lowest PNEC≥1 =0.1
100≥ MEC95/lowest PNEC>10 = 0.2
1000≥ MEC95/lowest PNEC>100 =0.5
MEC95/lowest PNEC>1000 = 1



Risk indicators

To address the spatial exposure aspects:

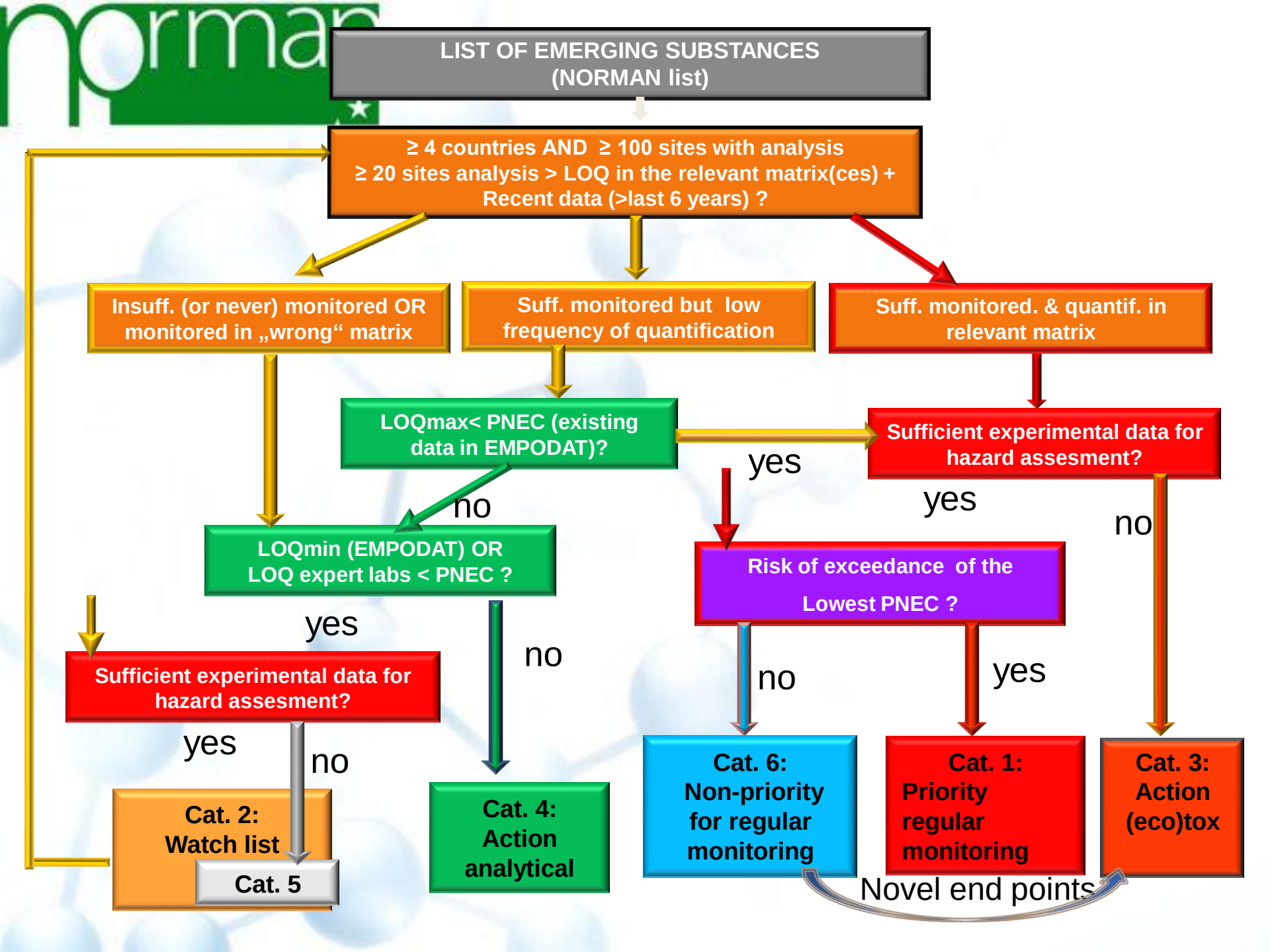
- *Frequency of Exceedance = n / N*

Where,

- *n is the number of sites with MECsite > Lowest PNEC*
- *N is the total number of sites where the substance was measured*

Score: value between 0 and 1

- Cat. 1, 3, 6: calculated using RECENT DATA
- Cat. 2, 4, 5: calculated using ALL DATA (all YEARS)


LIST OF EMERGING SUBSTANCES (NORMAN list)
≥ 4 countries AND ≥ 100 sites with analysis
≥ 20 sites analysis > LOQ in the relevant matrix(ces) +
Recent data (>last 6 years) ?
Insuff. (or never) monitored OR monitored in „wrong“ matrix
Suff. monitored but low frequency of quantification
Suff. monitored. & quantif. in relevant matrix
LOQmax< PNEC (existing data in EMPODAT)?
yes
Sufficient experimental data for hazard assesment?
yes
no
no
LOQmin (EMPODAT) OR LOQ expert labs < PNEC ?
yes
no
Sufficient experimental data for hazard assesment?
yes
no
Risk of exceedance of the Lowest PNEC ?
no
yes
Cat. 2: Watch list
Cat. 5
Cat. 4: Action analytical
Cat. 6: Non-priority for regular monitoring
Cat. 1: Priority regular monitoring
Cat. 3: Action (eco)tox
Novel end points