Prioritisation of emerging contaminants by action category: the NORMAN approach

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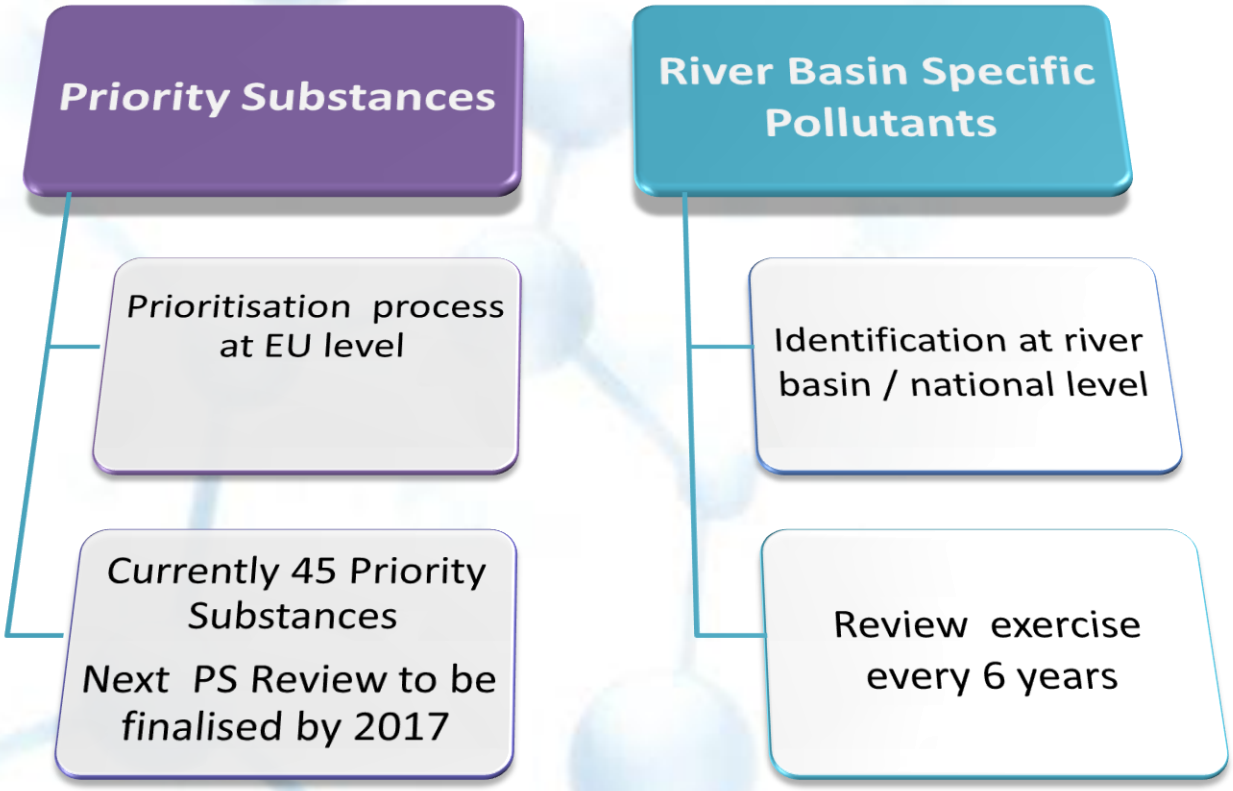
Regulated Pollutants under WFD



<u>Protection objectives:</u>

Aquatic ecosystems and human health via the aquatic environment

Last WFD PS review process (DG ENV)

overall approach to

Monitoring

Substances monitored by at least 4 countries

Compilation of manageable list of substances

Assess exposure (monitoring) and effect data

Use only experimental data

Prioritisation algorithm (PEC/PNEC ratio)

A posteriori check

Selection of highest ranked substances

Modelling

Substances from MS monitoring data + REACH SVHC, PBT/vPvB, pesticides Biocides, etc.

Compilation of manageable list of substances

Assess exposure (based on production / use) and effect data

Reliance on QSARs to fill data gaps

Risk ranking (PEC/PNEC ratio)

Expert review

Selection of highest ranked substances

Expert review

Final list of PS ⟷ **Establish final EQS**

Experience / lessons learnt

- More than 50% of candidate substances were discarded
- Lack of data or insufficient data reliability (e.g. LOD >> PNEC, non-relevant matrix, etc.)
- Strong bias towards already regulated pollutants
- Ever growing list of chemical compounds frequently discussed as “emerging substances”
- Existing knowledge gaps do not allow an emerging substance to be correctly evaluated and may lead to it being discarded or overlooked
- Dir 2013/39/EU ➔ A EU Watch List will be implemented

➔ **NORMAN prioritisation scheme**

NORMAN prioritisation scheme

- Designed **for emerging substances**
- Addresses **knowledge gaps**
- Identifies **actions needed**

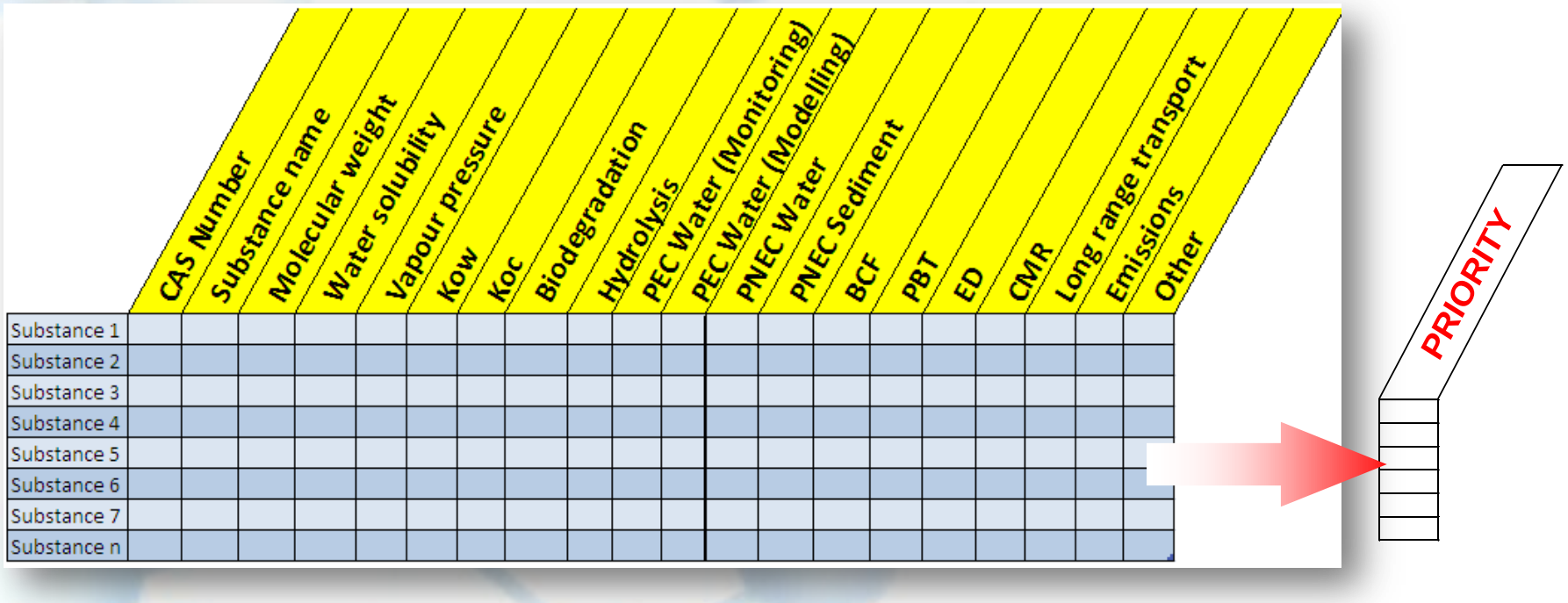
How does it work?

Photo nº 897 : Le tri du courrier, à la grande Poste, rue Jeanne d'Arc, vers 1935.

Typical steps / components of prioritisation schemes

Choosing the candidate substances

Choosing the relevant parameters for prioritisation

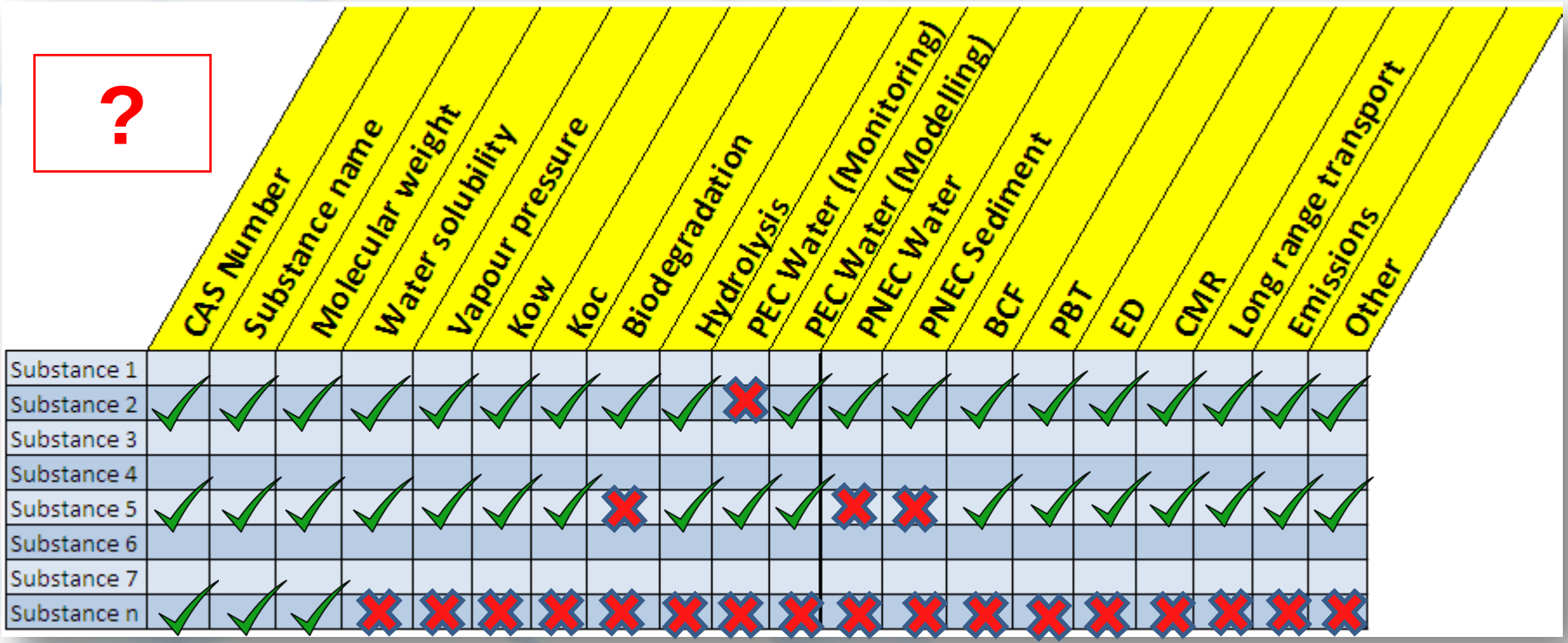


Filling in the database

Prioritisation algorithm

Adapted from V. Bonnomet , 2006

What to do when data is missing ?



Frequent conclusion of prioritisation exercises:

"…A large number of chemicals could not be prioritised due to a lack of either hazard or exposure data (or both)" (A. James. et al., 2009)

NORMAN approach: two main steps to tackle the problem of missing data

1. **Categorisation** of substances into action categories based on ***identified knowledge gaps***

2. **Prioritisation** of substances within each category for ***further action***

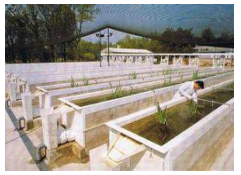
Categorisation of substances by identified knowledge gaps

Action categories

1. Control / mitigation measures

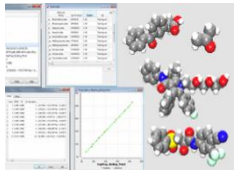
2. Screening campaigns

3. Rigorous hazard assessment



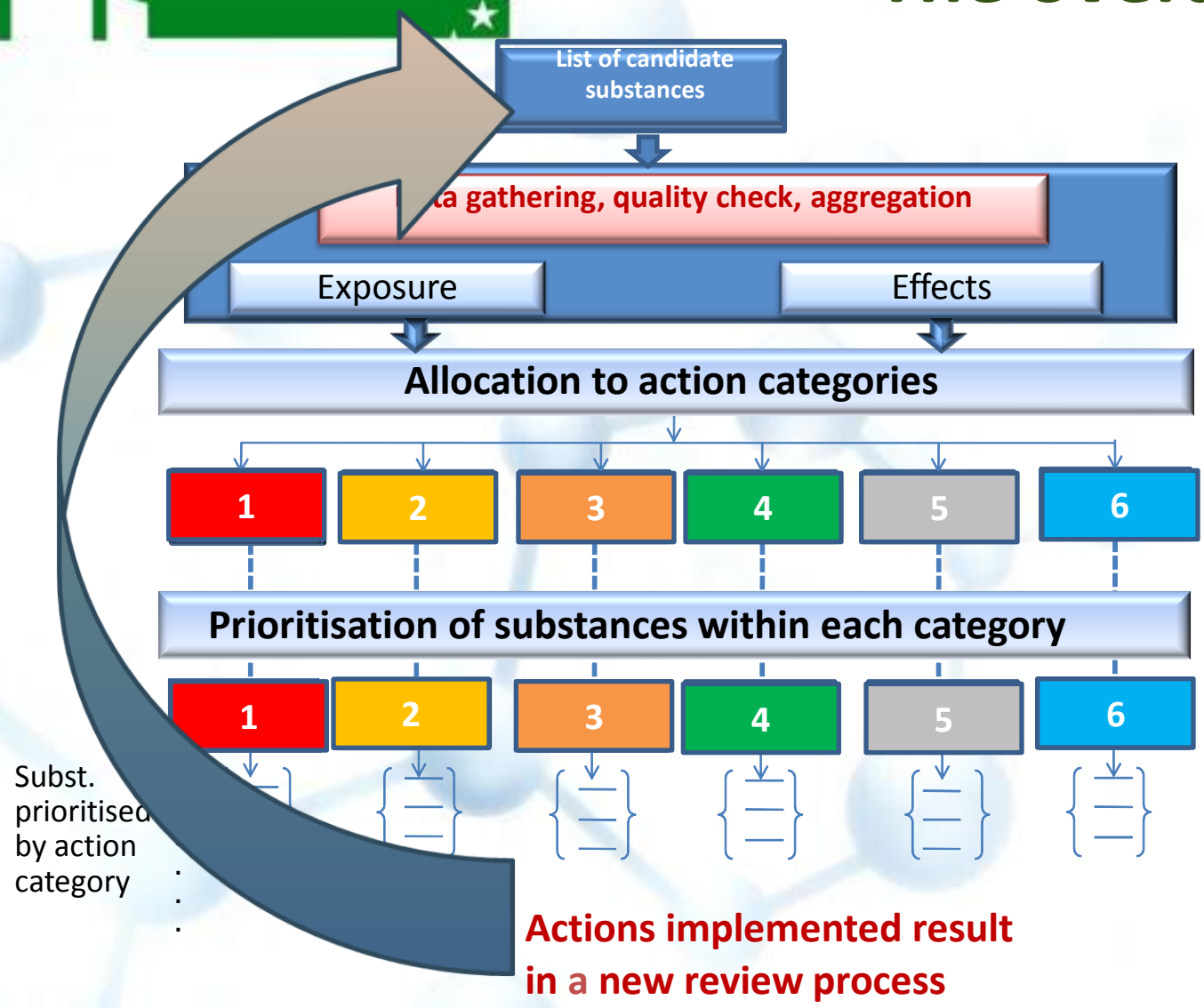
4. Improvement of analytical methods

5. Screening AND hazard assessment



6. Reduced monitoring efforts

The overall approach



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

2. Prioritisation – to define priorities within each action category

Risk indicators

Extent of Exceedance = MEC95 / Lowest PNEC

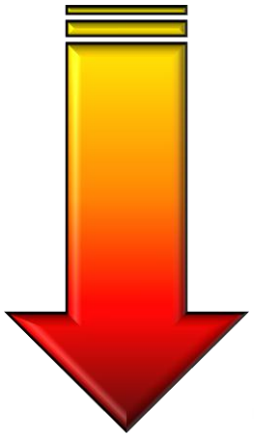
to address the intensity of impact

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

Frequency of Exceedance = n / N

to address the spatial exposure aspects

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

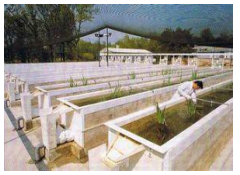
- Cat. 1, 3, 6: calculated using RECENT DATA
- Cat. 2, 4, 5: calculated using ALL DATA (all YEARS)

Implementation: The French Watch List

1. Control / mitigation measures

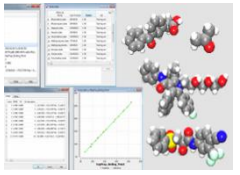
2. Screening campaigns

3. Rigorous hazard assessment



4. Improvement of analytical methods

5. Screening AND hazard assessment



6. Reduced monitoring efforts

Implementation: The French Watch List

Strong points

1. We were able to **select** compounds with high scores due to **hazardous properties,** which were **never monitored** in FR (by the Water Agencies)

Examples:

- **Triclocarbam, Triclosan,**

- **Parabens,**

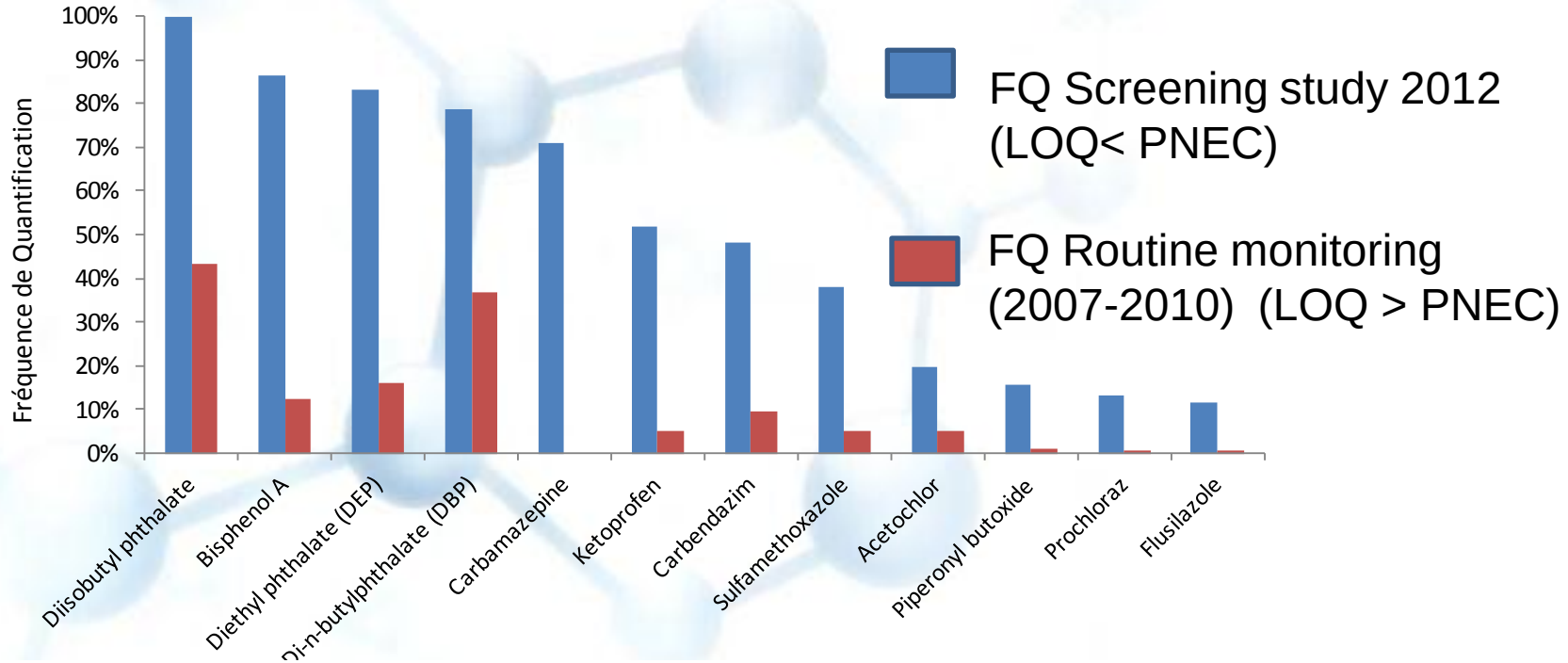
- **Amiodarone**, etc.

High occurrence frequencies observed during the screening study
➔ **will be included in the French Watch List for routine monitoring**

Implementation: The French Watch List

Strong points

2. We were able to **identify** compounds **already monitored** in FR, which were measured with **insufficient analytical performance**



Much higher FQ observed during the screening study

➔ **will be included in the French Watch List for routine monitoring**

Implementation: The French Watch List

Weak points

- **A robust exposure index for compounds not yet monitored is still missing** (under development within NORMAN Prioritisation WG):
  - Inclusion of an exposure index based on **production / usage (i.e. tonnages) and use pattern** would allow improved prioritisation of compounds never monitored but expected to be present in the aquatic compartment
- More systematic consideration of:
  - **metabolites and transformation products** (associated to parent compounds on the list)
  - Form in the **commercial product** vs **form present in the aquatic environment**

Conclusions

The NORMAN Prioritisation framework:

- is applicable at different geographical scales (European, national, river basin level)
- provides a decision-support framework for updating lists of substances for which actions (reduction, monitoring, research) are to be undertaken as a matter of priority
- Improvement needed as regards:
  - Integration with chemical screening and bioassays-based tools in order to improve the list of candidate substances
  - Exposure index: introduction of a surrogate for missing monitoring data at EU level
  - Going beyond PEC/PNEC ratios for individual substances

Thank you for your attention

Leaders of the activity	
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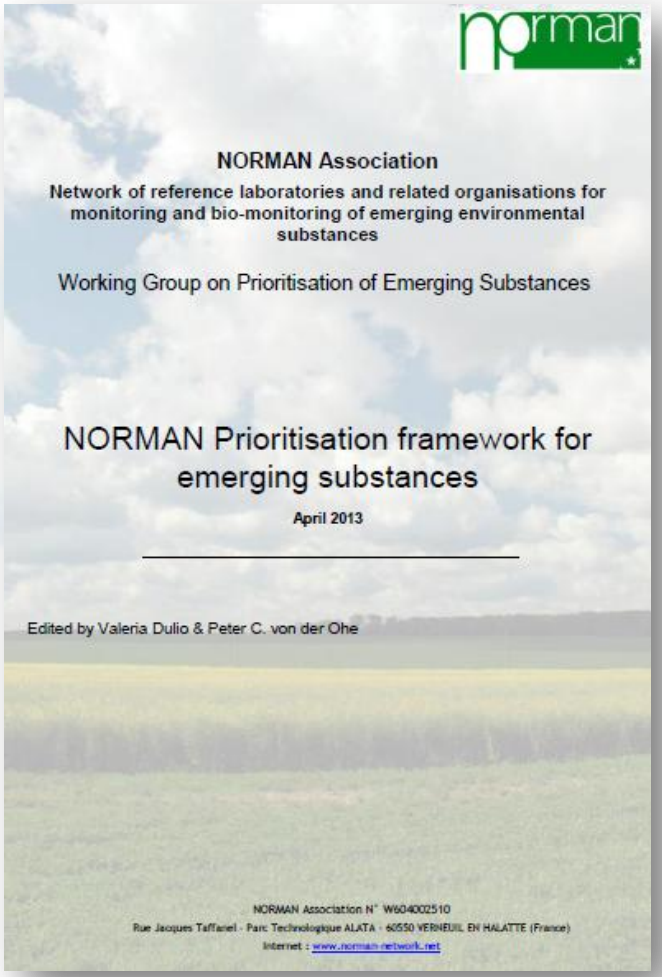
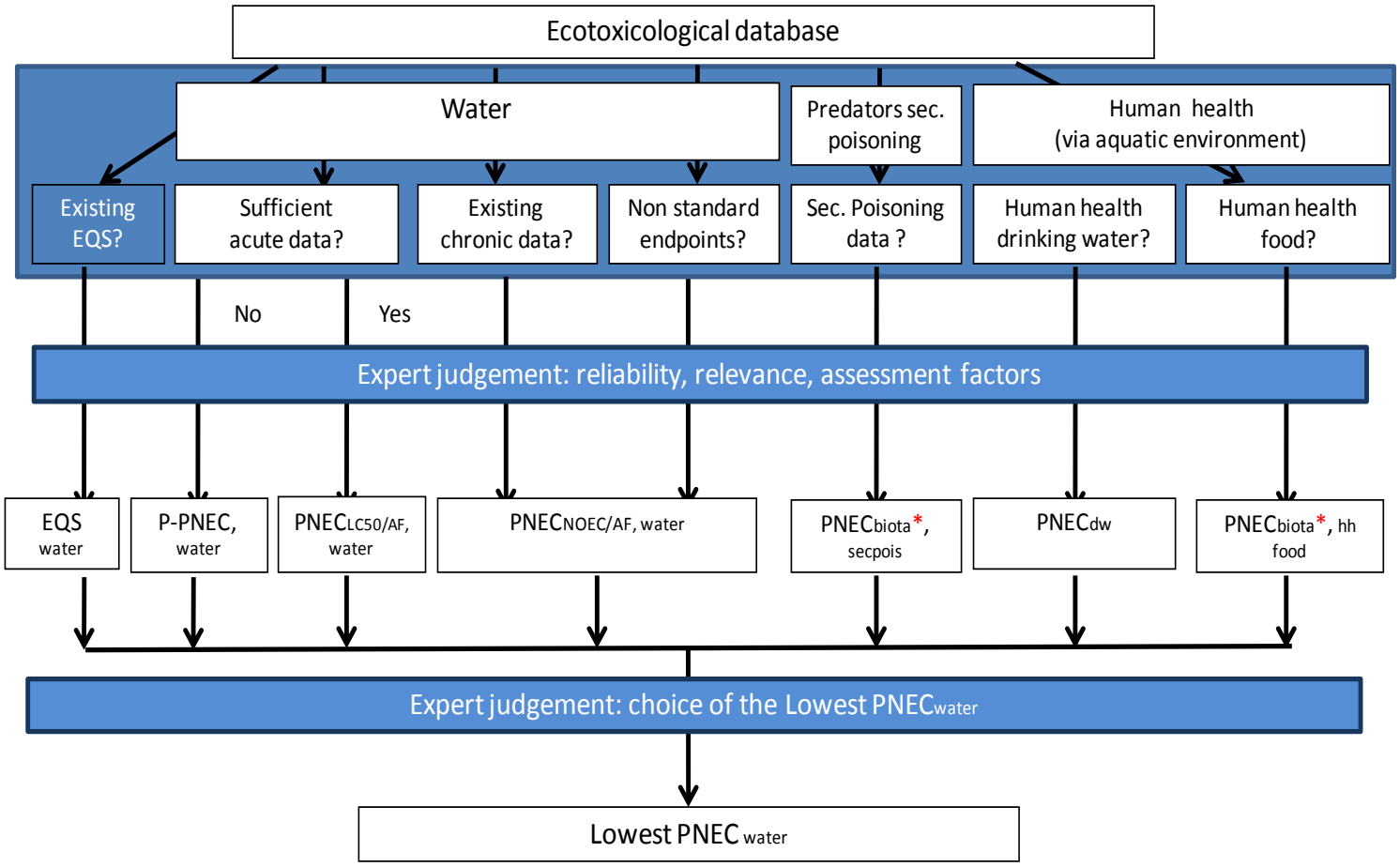


Margin for improvement

- Candidate substances
  - We cannot prioritise the contaminants we are not looking for ➔ need to integrate input from non-target screening, EDA, etc.
- Exposure index
  - Surrogate for missing monitoring data at EU level
  - Verify predicted exposure vs observed exposure
- Effect data
  - Improved criteria for the assessment of reliability and relevance of available tests
  - System for the derivation of provisional estimated PNEC (P-PNEC)
- Improved risk assessment
  - Going beyond PEC/PNEC ratios for individual substances, -
  - Identification of mixture drivers

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)

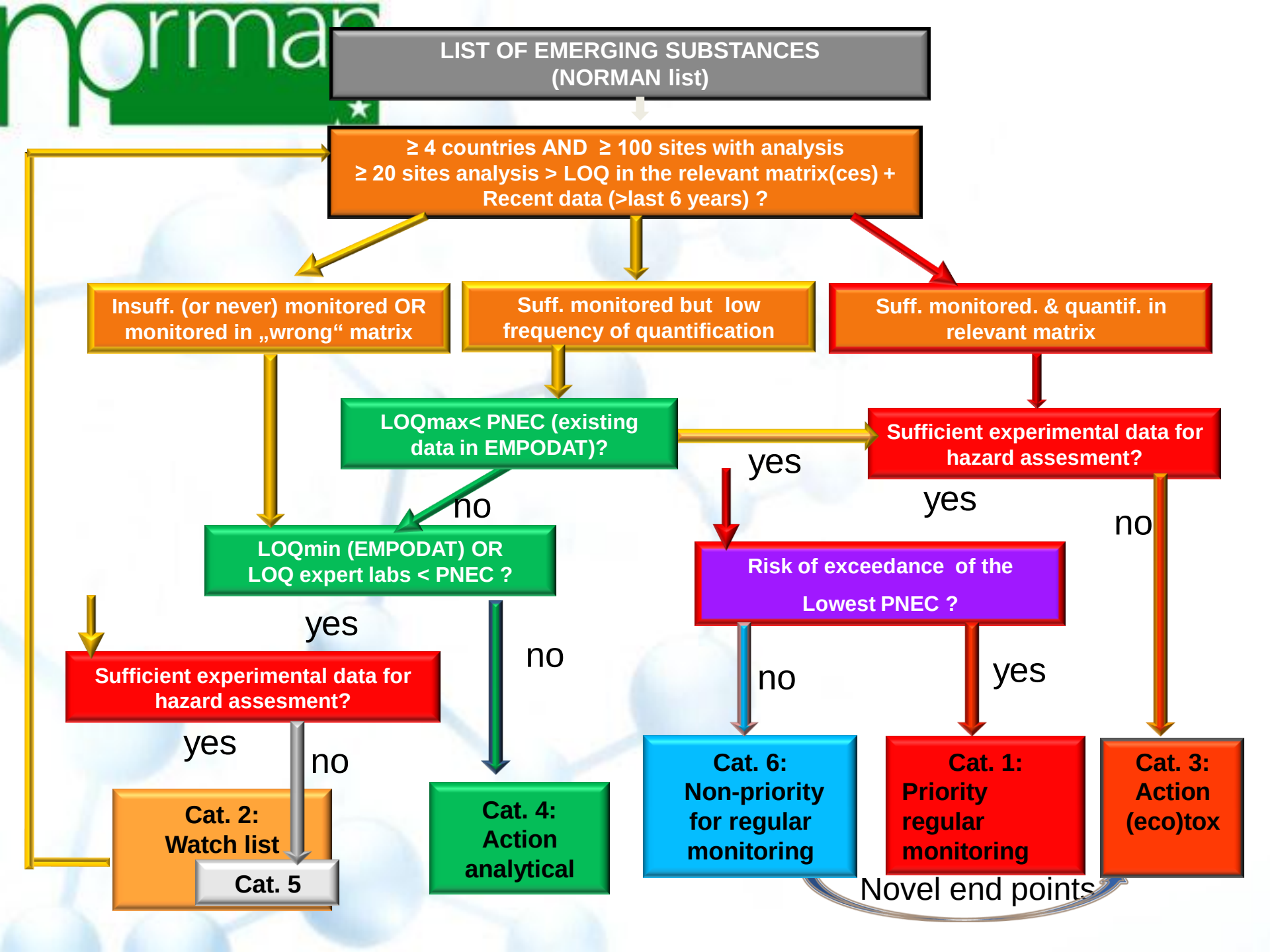
Final ED score: value between 0 and 1

Proven ED effect : 1

Suspect ED effect: 0.5

Not examined: 0.25

Examined and classified as not ED: 0


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
no
Sufficient experimental data for hazard assesment?
yes
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

Main critical steps in prioritisation

Selection of the relevant parameters / indicators

- Exposure: concentration, emissions…
- Hazard: effects on the ecosystems (PNECs), ED, CMR, PBT, …
- Physico-chem: solubility, biodegradability, Koc, Kow….

Candidate substances

No chance to identify priority compounds if not included in the list of candidate subst.

Filling of database

- data gathering
- quality check
- data aggregation

Prioritisation algorithm

- Choice of the algorithm
- Weight of the indicators