HBM4EU

science and policy
for a healthy future

Meta-analysis of interviews with experts, policy makers and stakeholders

current opinions and perceptions, ideas on policy options and future directions.

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Semi-structured interviews with key respondents

Perspectives	Number of interviews/ interviewees
Experts on phthalates and bisphenols from the consortium	4/6
EU policy makers (DG's and agencies)	6/8
Industry	3/9
NGO's	3/3
	16/27

Main objective of the interviews:

- Map perspectives on the topic as a preparatory step for a dialogue at the workshop

** A meta-analysis of these interviews will be reported as part of a deliverable on the case study on phthalates and bisphenols (due in February '19) – respondents will have the opportunity to provide their feedback on the draft report.*

Three main topics discussed in interviews

A. The current **scientific evidence base** on phthalates and bisphenols.
B. **Challenges and obstacles** for policy making on phthalates and bisphenols, and the (potential) role of **HBM(4EU).**
C. The relevance of different **policy instruments** and **good practices** (at EU and national level).

Main conclusions from interviews

A. On the evidence base…*

- Both substance groups have been studied for many years…
  This makes it 'old', but **prototypical cases**.

- Phthalates: there appears to be a growing scientific and societal consensus. Best illustrated by the current restriction proposal for four phthalates.
  - ⇒ Willingness to discuss challenges and obstacles for implementation of the restriction by most respondents, as well as the potential relevance of other (supporting) policy instruments.

- Debate on bisphenols (BPA) seems to remain more controversial.
  - ⇒ Less willingness to discuss policy options by some respondents, except large-scale research (e.g. Clarity studies in US, HBM4EU?)

** Statements in these slides are only based on a meta-analysis of the interviews (= perceptions, opinions), not on a scientific evaluation.*

Main conclusions from interviews

Phthalates: often heard arguments/milestones

- **Innovation: HBM-data** (DEMOCOPHES) used in HIA as a basis for the restriction proposal for four phthalates, taking into account **combined effects** of exposure to these four phthalates. (Approx. 5% of children in EU at risk, in 2011)
    - "The history of the phthalates case illustrates the importance of good quality data to support regulatory policy making."

- Nevertheless: the scientific methodology for assessing the combined effects is still much debated.
    - → "Making better use of HBM-data could be (part of) the solution"

- While others argue that it is all too little, too slow. ("only 4 of the 10 phthalates on the SVHC list included"; "FCM excluded"; etc.)

Main conclusions from interviews

Bisphenols: often heard arguments/milestones

- Persistent controversy, fuelled by the **discrepancy** between:
  - standardised **regulatory studies** (used for formal risk assessments) that do not report health effects,
  - and an increasing number of **academic studies** reporting effects (but lacking reproducibility – therefore not meeting the quality standards for regulatory risk assessment).

- A large-scale study in the US (**Clarity**) aims to bridge this discrepancy, but has not yet been able to bridge the controversy.
- BPA was added to the **SVHC list** and its use in **thermal paper** (e.g. cash receipts) will be banned from 2020 onwards.
- EFSA's risk assessment for BPA in **food and FCM** has been revised in 2015 (introducing considerably lower TDI's) but still concludes that there is no health risk from BPA from food intake at current exposure levels.

Main conclusions from interviews

- However, the controversy does not so much relate to the specific substances, but rather to the 'wider context':
  - "The **slow process** of substance-by-substance assessments."
  - "The **lack of knowledge** on mixtures and cumulative exposure."
  - "The **fragmented management** (in the different policy silos) and implementation gaps."
  - "Divergent judgements on how to deal with **uncertainties** and the need for **precautionary policy** initiatives."
  - "The lack of **transparency**."

- Nevertheless, the phthalates and bisphenols cases are found to be good cases to track progress in this respect (prototypes).
- And HBM is judged to be an important 'trigger' for innovation:
  - 'To show **real life/actual exposures**'
  - 'To triggering a more **holistic approach**'

Main conclusions from interviews

B. Challenges for policy making and the ro[illegible] f[illegible] HBM(4EU) – topics for debate:

The phthalates case as a good example!

I. How to deal with HBM data in risk assessment and regulation? (*'How to reconcile a holistic approach with compartmentalised policy making?'*)

- "Do the procedures have to be adjusted? (make use of HBM compulsory, define quality requirements, develop routines)"
- "Will good quality data find its way automatically?"
- "Should joint reflection across policy domains be organised more frequently/more structurally?"
- "Do we have to identify policy opportunities more actively?"

- [*What difference will it make for risk management?*]
- [*Which role for HBM4EU?*]

Main conclusions from interviews

B. Challenges for policy making and the role of HBM(4EU) – topics for debate:

II. How to communicate on phthalates and bisphenols in a context of uncertainty?

- Communication on HBM data – by scientists
- Communication as a policy instrument, e.g. for awareness raising. – by policy makers
- Communication to build trust in EU, science, the market, … – as a collective endeavour

- [*Citizens right to be informed + Citizens expectation to be informed by governments (as a trusted information source).*]
- [*Importance of nuanced communication, not causing unnecessary fear or 'chemophobia'*]
- [*Joint reflection on main messages recommended*]

Main conclusions from interviews

B. Challenges for policy making and the role of HBM(4EU) – topics for debate:

III. **How can HBM(4EU) help to build trust of citizens in the regulatory system?** (as well as trust in science, EU industry, the market, …)

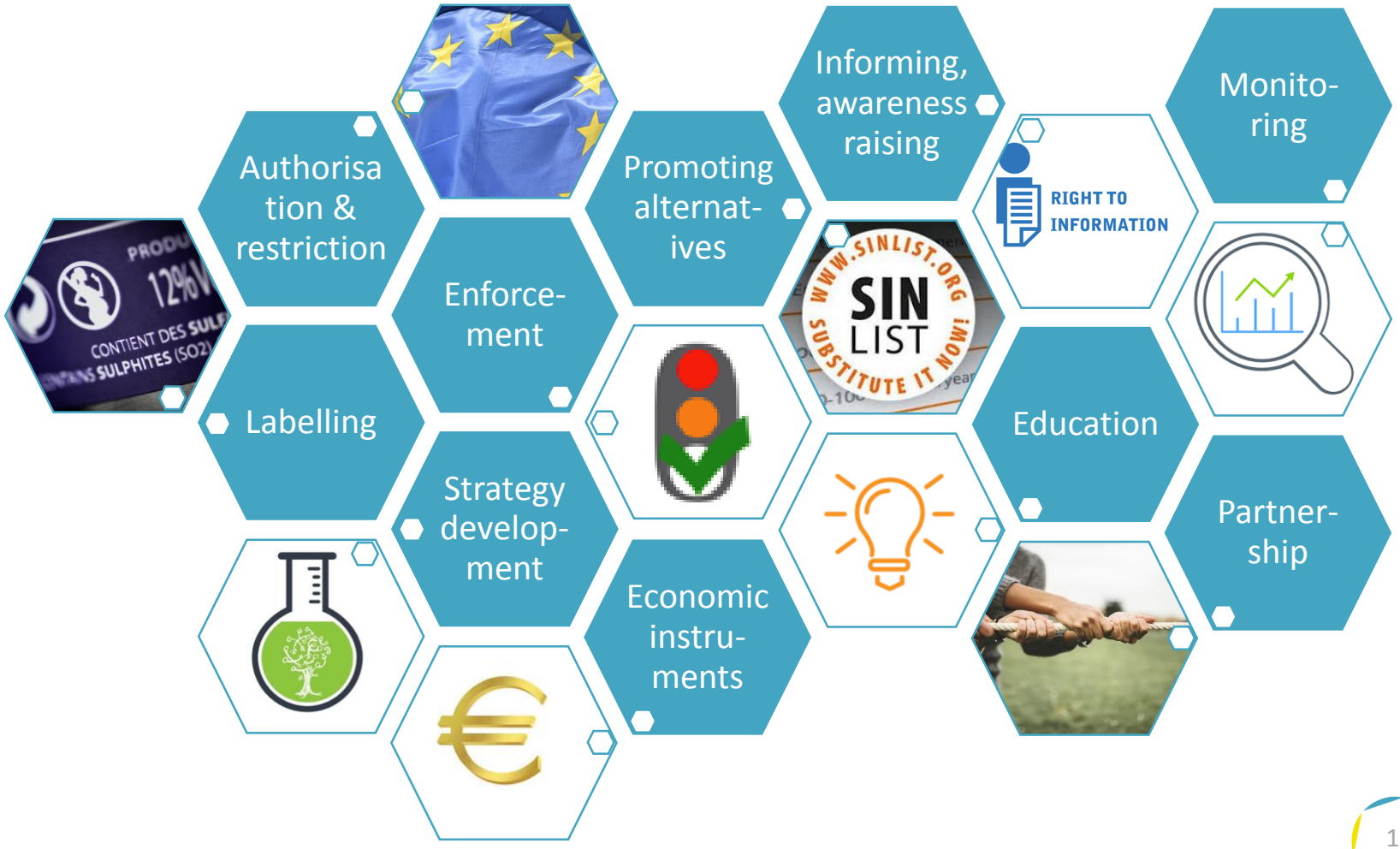
IV. **Can HBM data help to prioritise attention?** (Most problematic substances? Or also vulnerable/high exposed groups or profiles?)

V. **What other policy instruments/actions gain legitimacy by the HBM-evidence on phthalates and bisphenols?**

- Phthalates: all instruments that can support the phasing out of restricted phthalates?
- Bisphenols: minimally monitoring and informing the public?

Main conclusions from interviews

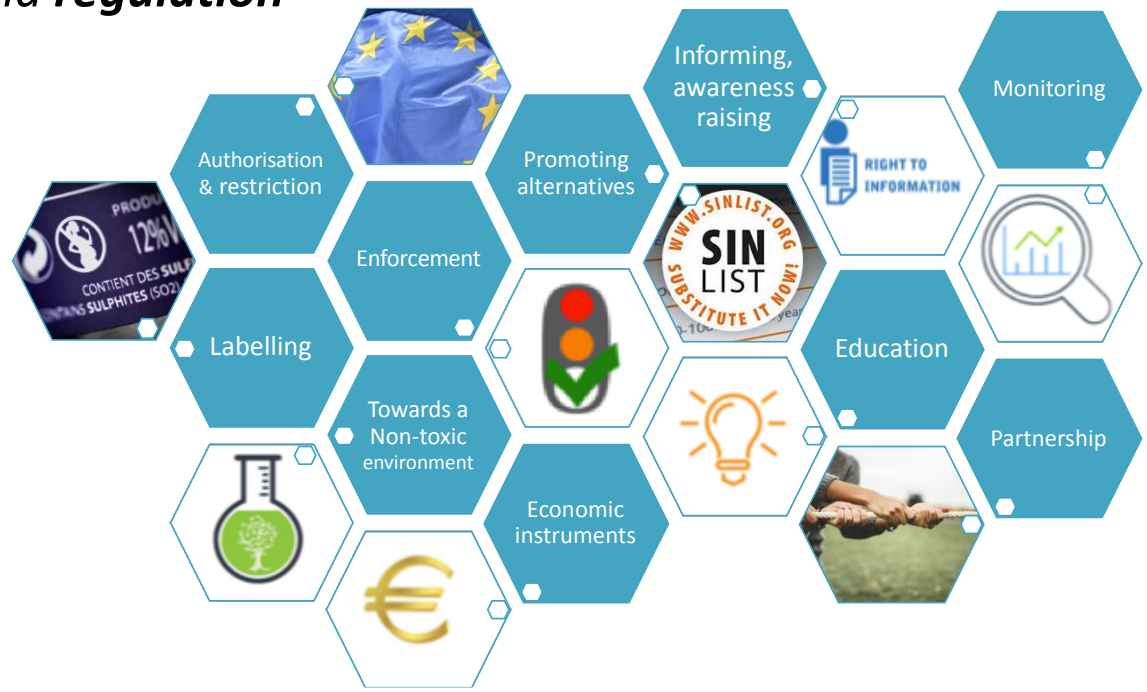
C. Identified policy instruments and good practices



How can HBM4EU support policy making?

*I. How to deal with HBM data in **risk assessment** and **regulation***

*II. How to **communicate** on phthalates and bisphenols (in a context of uncertainty)*



*V. Which **actions** gain legitimacy by HBM-evidence?*

*IV. Can HBM data be used to **prioritise** our attention?*

*III. Can HBM4EU help to build **trust** of citizens in EU, science, market, …*

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