Vitenskapskomiteen for mat og miljø

Norwegian Scientific Committee for Food and Environment

Collaboration to **H**armonise the **A**ssessment of **N**ext **G**eneration **E**vidence (CHANGE) – 55th Focal Point Meeting 11-12 September 2024

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What went down in Oslo? ☺

"Well-organized workshop, and the approach to the subject was refreshing to say the least. Most workshops seem to re- and re-invent the wheel with pointing at the perceived barrier for regulatory NAM uptake as major outcome, not this one, well done."

"The extensive engagement with other attendees, many of whom I did not know. Such engagement across sectors and affiliations is the path forward on NAMs. Certainly, there have been other meetings across sectors but not of this format and not designed to elicit such personal observations. Also, having a three year plan with additional workshops is a brilliant. It brings a continuity to the engagement that allows individual participants to build NAMs related collaborations. These collaborations can represent swirls of change that fold into the broader effort."

CHANGE

The Norwegian Scientific Committee for Food and Environment (VKM)

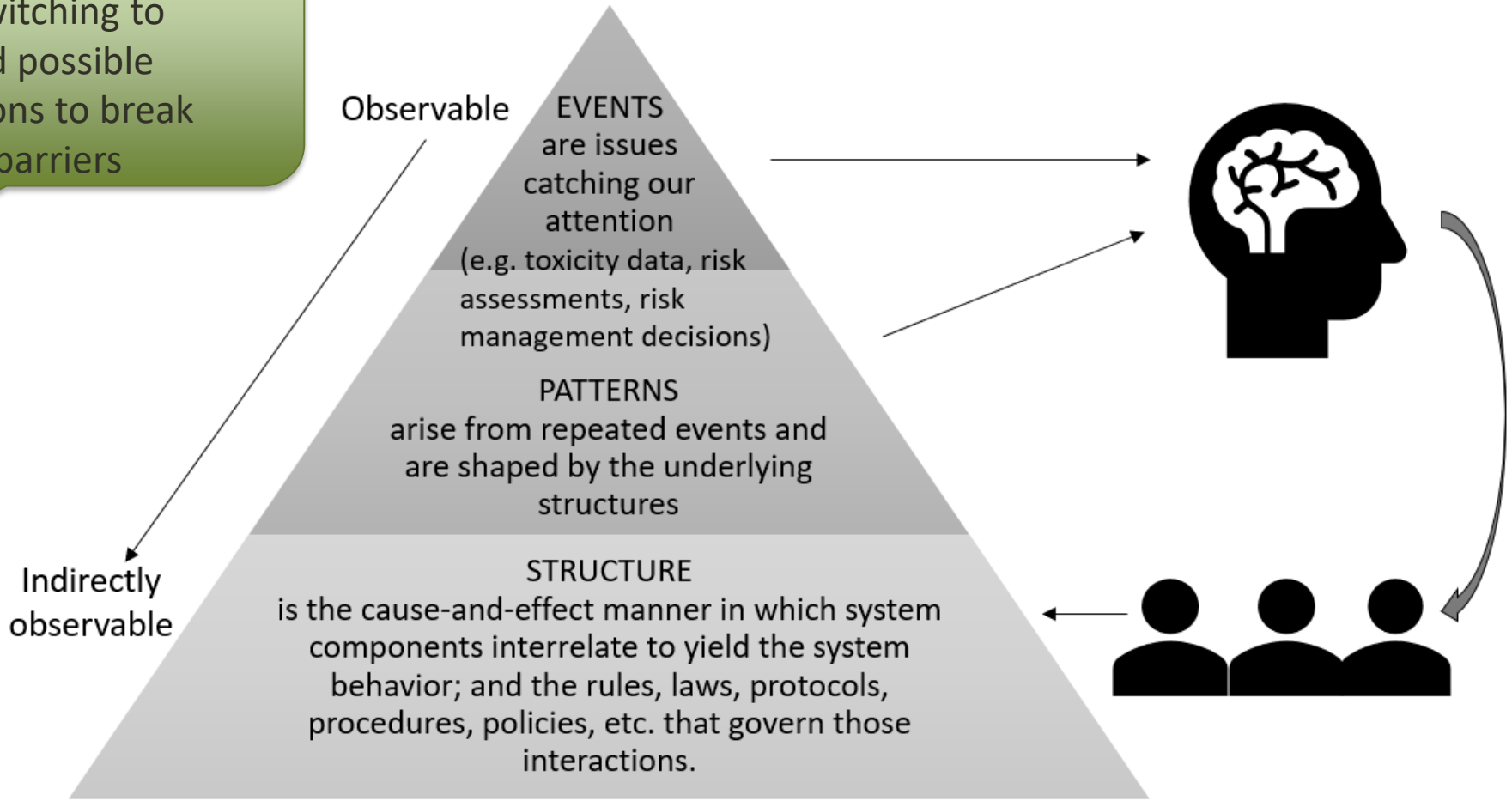
Evidence-Based Toxicology Collaboration (EBTC)

Financed by EFSA (Country Specific Tailor-Made Activity)

3 workshops (2024-2026) / Establish a network that will continue working with the outcome of the workshops

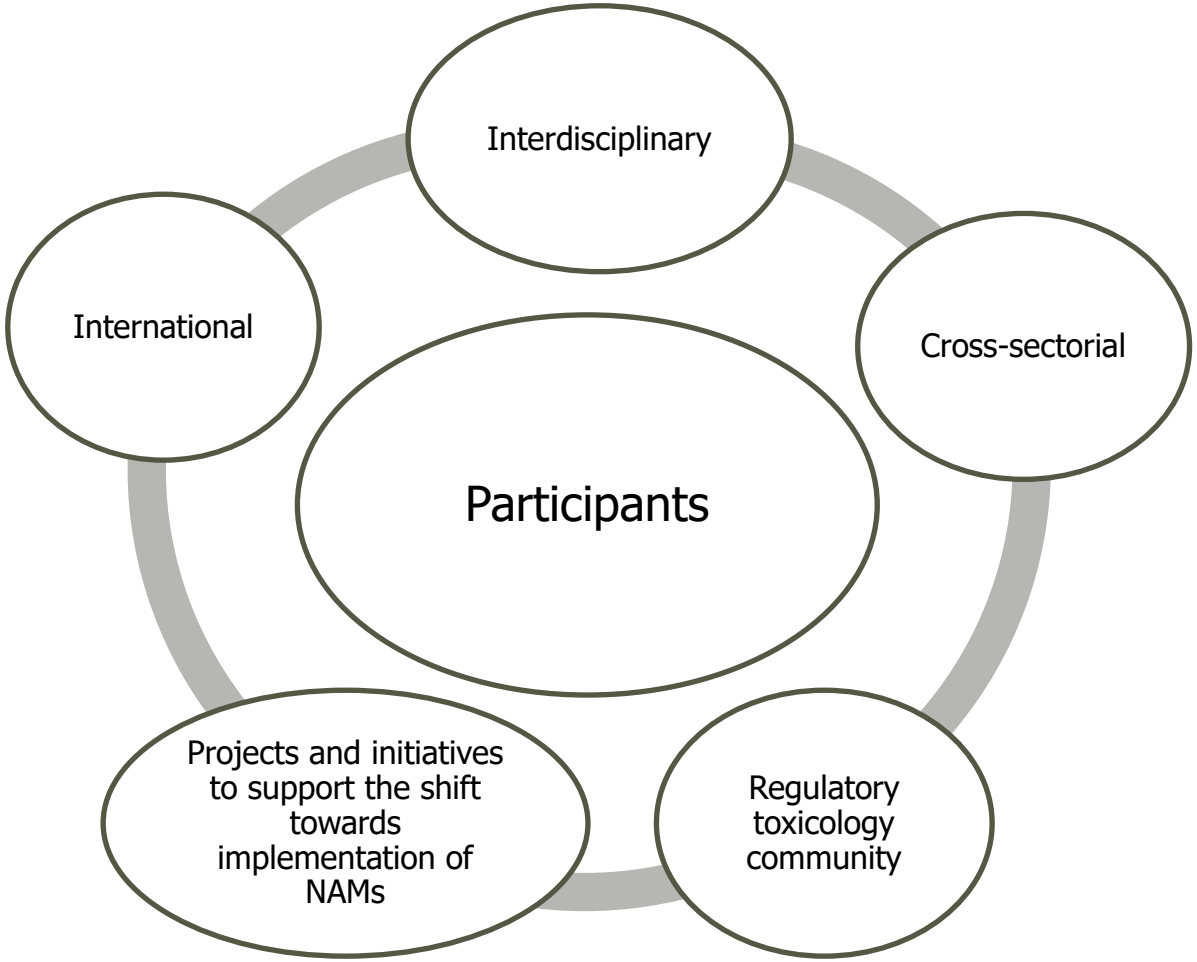
CHANGE – A systems-based approach

Identify barriers that prevent switching to NAMs, and possible interventions to break down the barriers



People in the system and their experiences, perceptions, values, beliefs, …

CHANGE, who?


Interdisciplinary
International
Cross-sectorial
Participants
Projects and initiatives to support the shift towards implementation of NAMs
Regulatory toxicology community

CHANGE, why?

System related factors, such as structural and cultural issues e.g. shaping people's behaviours, perceptions, decisions, involvement, and interactions with others,

may be of importance for the lagging of the transition from animal studies to NAMs

CHANGE, what?

- Focus on the people working in the chemical regulatory system
- Identify system-related factors they experience to be challenges/barriers for transition towards NGRA
- Identify and prioritise achievable actions for breaking down the barriers
- Identify broad consensus on fundamental issues of importance for the transition
- Build on and synergize with relevant ongoing projects across the globe
- Avoid duplication of already ongoing work

Illustrating possible system related barriers

- Human health
- Environment
- Other

- Risk management
- Risk assessment
- Research
- Other

- Non-governmental
- Governmental
- Agencies
- Authorities
- Academia
- Other
- Industry

- Plant protection products
- Biocidals
- Cosmetics
- Industrial chemicals
- Food additives
- Feed additives
- Other

- Statistics
- Toxicology
- Biochemistry
- Chemistry
- Epidemiology
- Human medicine
- Veterinary medicine
- *Evidence-based toxicology*
- *NAMs*
- *AOPs and IATAs*
- *AI*
- *Computer science*
- Other

Silos

↑ Solve the need for specialisation

↓ Potential challenges

- Sufficiently connected?
- Familiar with and responsive to each other needs?
- (Incorrect) assumptions about each others needs?
- Will the transition to NAMs increase the complexity of the system because there is a need for additional expertise in the different silos?
- Availability of competence?

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Goal and deliverable for the project

Final deliverable: A White Paper of actionable policy recommendations

Overall goal: Contribute to regulatory acceptance and implementation of NAM data

Organisation or the work during the 3 years

Project group: VKM and EBTC

Convening Committee (Europe, United States, Australia; in total 23 participants)
(2 meetings October 2023)

Advisory Board (Europe, United States, Australia) (3 years, monthly meetings)

The Advisory Board:
Provide strategic guidance and support, and share information about ongoing related projects to ensure that they complement each other

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Project Group

- Heather Ames
- Angela Bearth
- Trine Husøy
- Gro Mathisen
- Camilla Svendsen
- Gunn Vist
- Paul Whaley
- Sebastian Hoffmann
- Katya Tsaioun
- Lowenna Jones
- Gisle Solstad

Advisory Board

- Didier Verloo, EFSA
- Andrew Rooney, NIEHS
- Thomas Hartung, Center for Alternatives to Animal Testing, Johns Hopkins
- Denise Bloch, BfR
- Kris Thayer, US EPA
- Weihsueh Chiu, Texas AMU
- Ulla Simanainen, ECHA
- Aleksandra Cavoski, Birmingham University (PrecisionTox)
- Ovnair Sepai, UK Health Security Agency
- Erwin Roggen, 3Rs Management and Consulting ApS; (ONTOX)
- Miles Davenport, University of New South Wales
- Christophe Rousselle, ANSES (PARC)
- Fred Wright , North Carolina State University
- Kannan Krishnan, California Environmental Protection Agency
- Arianna Giusti, Cosmetics Europe
- Jennifer Sass, Natural Resources Defense Council; George Washington University
- Suzanne C Fitzpatrick, US FDA
- Holly Davies, Washington State Department of Health
- Weida Tong, US FDA
- Takao Ashikaga, JACVAM
- Yoko Hirabayashi, JACVAM
- Helena Hogberg-Durdock, NICEATM, NIEHS
- Rashmi Joglekar, University of California San Francisco
- Hajime Kojima, JACVAM
- Olivia Osborne, Food Standards Agency
- Daniele Wikoff, ToxStrategies
- Seok “Soga” Kwon, the National University of Singapore

Asia (Japan, Singapore; 4)
Australia (1)
Europa (Frankrike, Norge, Sveits, Tyskland, UK; 6)
Nord-Amerika (USA; 13)
EFSA, ECHA, Cosmetics Europe (3)

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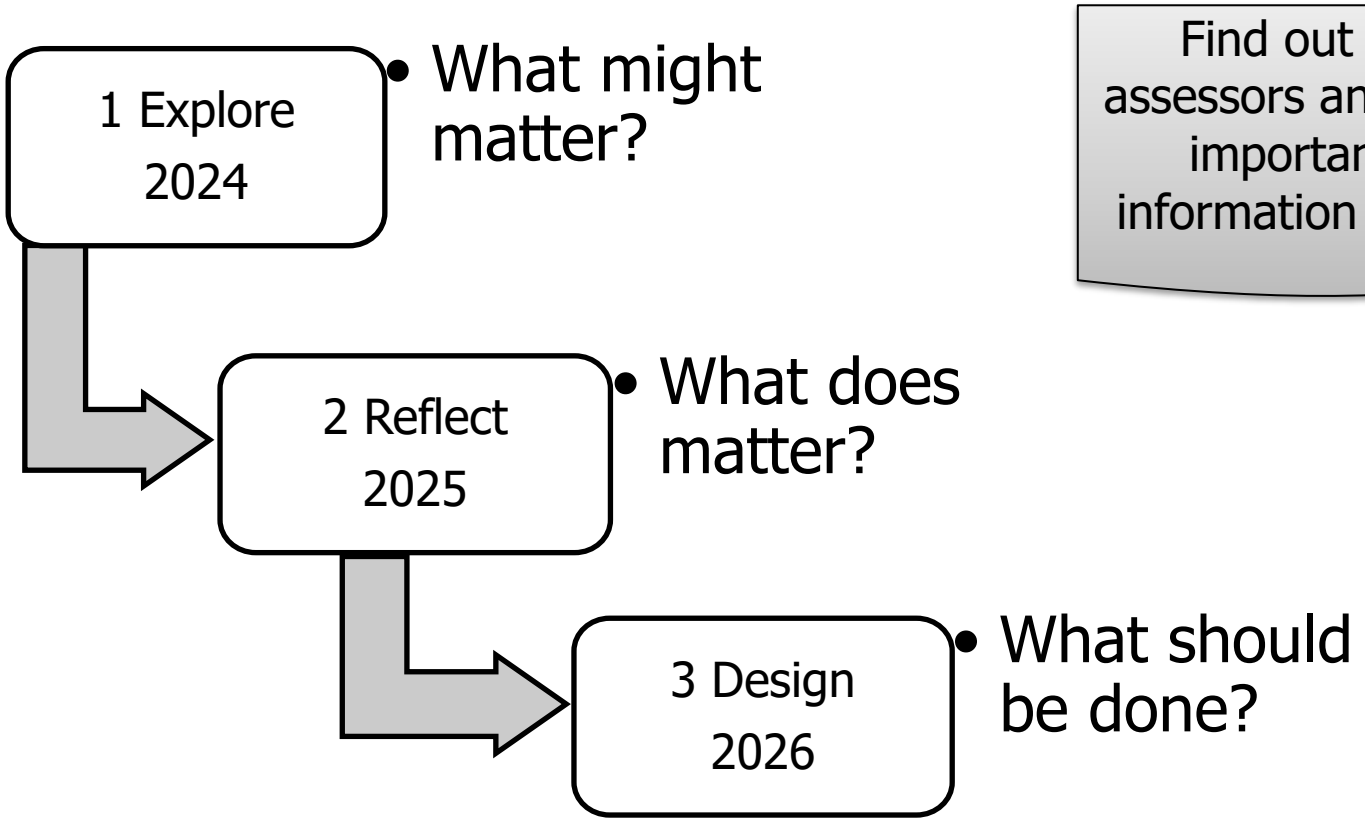
The workshop set up

System related factors including structural and cultural issues



Find out what risk managers, risk assessors and researchers think may be important. Share experiences on information needs and information flow

Get consensus on what is actually important

Prioritise practically achievable steps for action (white paper)

Participants in the workshops

- Risk managers
- Risk assessors
- Researchers

Success factors

- Appropriate balance of risk managers, risk assessors and researchers
- Broad international participation from all sectors
- High-level participation
- Involvement of social sciences

Workshop 1

Oslo 18.-20. June; lunch to lunch; 50 participants

BfR, Cosmetics Europe, US EPA, US FDA, Texas AMU, University of Birmingham, Natural Resources Defense Council, George Washington University, Washington State Department of Health, ToxStrategies, UK Food Standards Agency, NIEHS, North Carolina State University, ESTIV, ANSES, PARC, NIPH, Nordic Institute of Odontologic Materials, UK Health Security Agency, National Institute of Health Carlos III(ISCIII), 3RsMC ApS, Unilever, Altertox, California EPA, Swiss Centre for Applied Human Toxicology, Oregon State University, OECD, Wageningen University, Michigan State University, PrecisionTox, Lancaster University, Evidence-Based Toxicology Collaboration (Johns Hopkins), National University of Singapore, Vrije University, Safety and Health Technology Center, ASPIS, EFSA, …

List of participants available here on the CHANGE website

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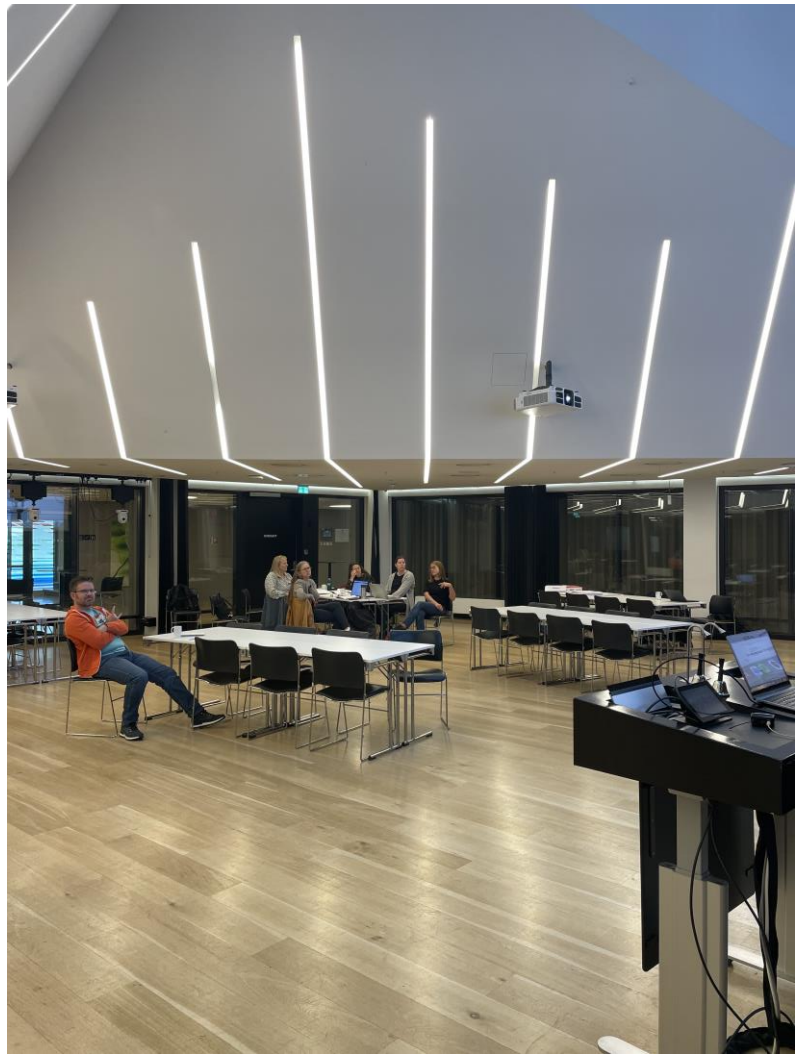
What did we do during the 3 days in Oslo?

Day 1	Create long–list of anecdotes (guidance themes one and two).	**Step 1**
Day 2	Keynote presentation for inspiration.	
	Create long–list of anecdotes (guidance themes three and four).	**Step 1**
	Create short-list of prioritised anecdotes.	**Step 2**
Day 3	Build up details of the prioritised anecdotes to get insight into the views from participants in different parts of the regulatory toxicology system.	**Step 3**
	Map prioritised anecdotes on underlying system-level factors.	
	Summary, next steps, and closing of workshop.	



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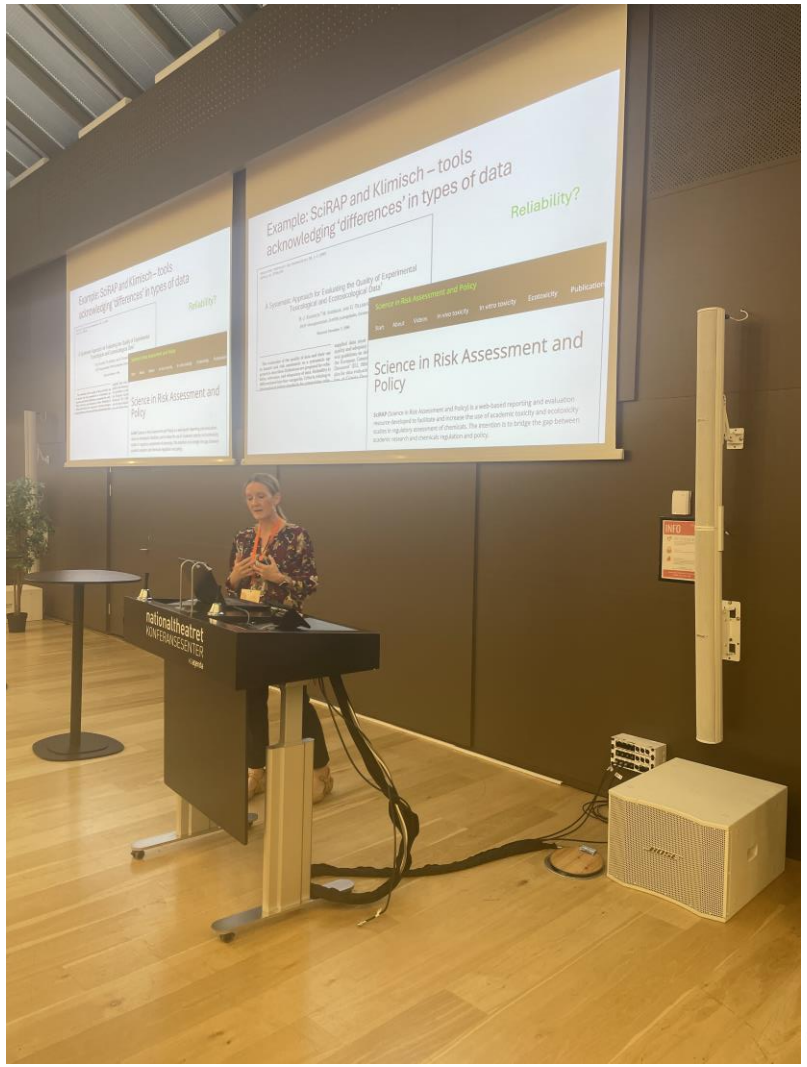
Day 1

Time (CEST)	Activity
12.00-13.00	Registration and lunch
13.00-13.30	Welcome *Harald Gjein* *Sebastian Hoffmann* Information *Project team*
13.30-13.45	Introduction of guidance theme "Prediction versus protection". *Arianna Giusti, Cosmetics Europe.*
13.45-14.45	Small group discussions. Free-form storytelling and brainstorming of anecdotes. Create a mind map for each anecdote.
14.45-15.15	Break
15.15-15.30	Introduction of guidance theme "Silos". *Denise Bloch, German Federal Institute for Risk Assessment (BfR).*
15.30-16.30	Small group discussions. Free-form storytelling and brainstorming of anecdotes. Create a mind map for each anecdote.
16.30-17.00	Break
17.00-18.00	Large group discussions (Fishbowl*). Free-form storytelling and brainstorming of anecdotes. Create a mind map for each anecdote.
18.00-18.15	Collect participant thoughts on day 1 and introduce the poster session. *Project team*
18.15-18.45	Mind map poster session. Participants contribute additional thoughts to the mind maps via post it notes.
19.00	Dinner



Day 2

Time (CEST)	Activity
08.45-09.00	Arrival
09.00-09.15	Welcome, summarise day 1 and introduce day 2. *Project team*
09.15-10.00	Keynote presentation Examining Values to Facilitate the Effective Use of NAMs in Regulatory Toxicology. *Kevin Elliott, Michigan State University.*
10.00-10.15	Introduction of guidance theme "Regulatory versus academic data". *Daniele Wikoff, ToxStrategies.*
10.15-11.15	Small group discussions. Free-form storytelling and brainstorming of anecdotes. Create a mind map for each anecdote.
11.15-11.45	Break
11.45-12.00	Introduction of guidance theme "Standard operating procedures". *Weihsueh Chiu, Texas A&M University.*
12.00-13.00	Small group discussions. Free-form storytelling and brainstorming of anecdotes. Create a mind map for each anecdote.
13.00-14.00	Lunch
14.00-15.00	Large group discussions (Fishbowl*). Free-form storytelling and brainstorming of anecdotes. Create a mind map for each anecdote.
15.00-15.30	Mind map poster session. Participants contribute additional thoughts to the mind maps via post it notes.
15.30-16.00	Break
16.00-16.15	Collect participant thoughts on day 2. Introduction of the prioritisation exercise. *Project team*
16:15-17.00	Prioritisation exercise. Identify anecdotes participants would like to discuss more.
19:00	Dinner

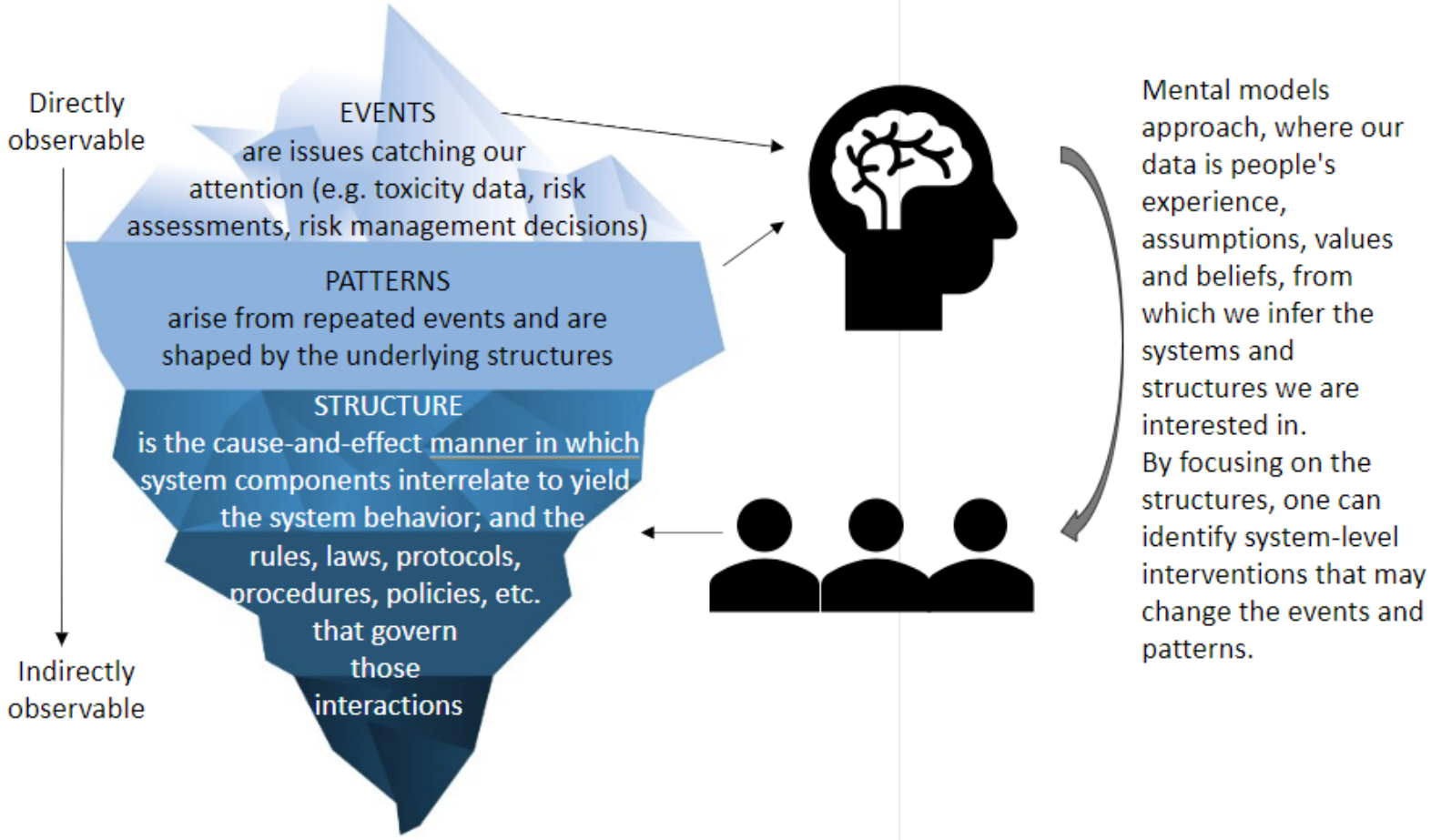
Day 3

Time (CEST)	Activity
08:45-09:00	Arrival
09:00-09:30	Welcome, summarise day 2 and introduce day 3. *Project team*
09:30-10:45	Small group discussions. Build up details of the prioritised anecdotes to get insight into the views from participants in different parts of the regulatory toxicology system.
10:45-11:15	Break
11:15-12:30	Small group discussions. Map prioritised anecdotes onto underlying system-level factors**.
12:30-13:00	Summary, next steps, and closing of workshop. *Project team*
13:00-14:00	Lunch

Format

- About 60 participants including the project group
- Small group discussions – Fishnbowls – Plenum discussions
- Recordings of all small goup discussions and fishbowls – Mindmaps – Blopmaps
- Why this format?
- Time to repeat the iceberg model:

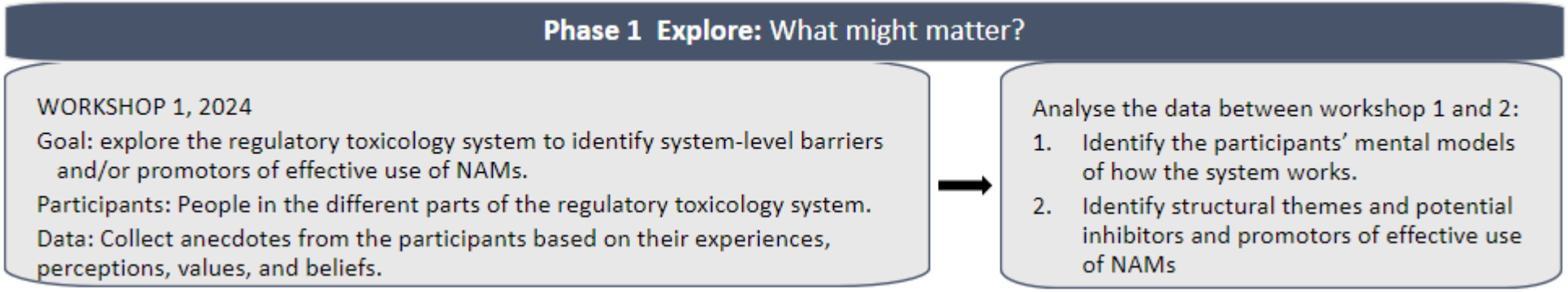
The iceberg model



Mental models approach, where our data is people's experience, assumptions, values and beliefs, from which we infer the systems and structures we are interested in.
By focusing on the structures, one can identify system-level interventions that may change the events and patterns.

The iceberg model

- For CHANGE, he iceberg model is inerpreted into a three-phase «explore – reflect – design» project.
- Workshop 1 is the «explore» phase, characerising the mental models of participants



After the workshop: Follow-up online workshops

- 3 follow-up online workshops take place in October
- The online workshops are arranged to enable involvement of more persons within the regulatory toxicology system in the CHANGE project, and to discuss and ask follow-up questions from the June-workshop.
- The online workshops will have a duration of 90 minutes.
- Representatives from, among others, JRC and EC are on-board for the events.
- More representatives from the industry are on-board for the events

Intermezzo – Use of AI

- The project uses extensively AI, both in the data capture and data analysis
  - **Data capture**: Whisper (OpenAI) is used to generate high quality transcripts from the workshop's recordings.
  - **Data analysis**: ATLAS.ti is used to carry out a two.step coding (inductive freestyle coding & flexible deductive coding) and thematic analysis.
- We are not able to present this at the upcoming AI symposium, but would be happy to do so at another occasion

Steps ahead: Analysis of the data

- June – July: Data preparation – Transcription of audio recordings and pseudonymisation of transcripts
- August: Developing codebook
- September: Testing and improve codebook – coding
- October: Data analysis and interpretation of findings
- November – February: Manuscript

- We are also working on a publication with focus on the methodologies used, inluding how they are percived by the Project Group, the Advisory Board and the participants.

Next workshop

- In Oslo, 24 – 26 June 2025
- The work in 2025 will mainly be focused on preparation for the workshop.

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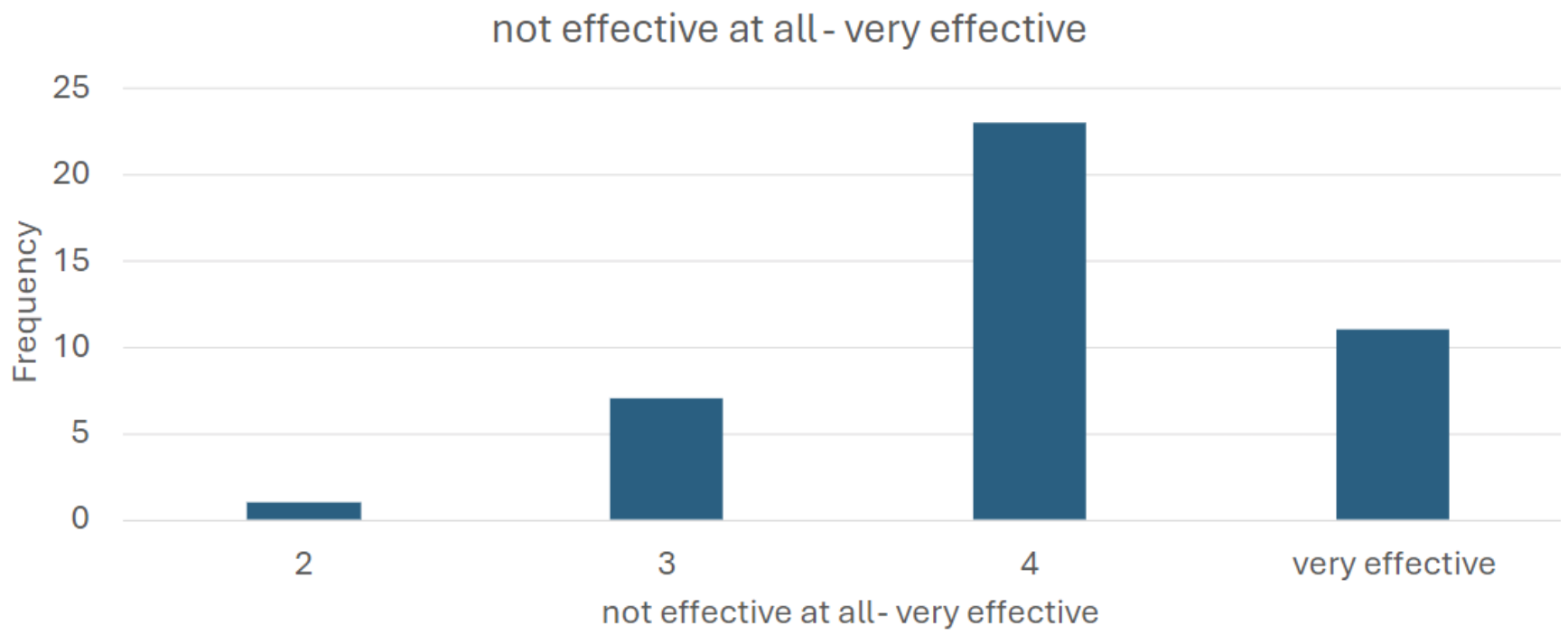
Evaluation - Overall

	1	2	3	4	5
1: poorly / 5: well-organised	-	-	-	1 (2%)	41 (98%)
1: boring / 5: interesting	-	-	-	5 (12%)	36 (88%)
1: dull / 5: enjoyable	-	-	-	6 (15%)	35 (85%)
1: not relevant to me / 5: relevant to me	-	-	1 (2%)	7 (17%)	33 (81%)
1: useless / 5: useful	-	-	1 (2%)	9 (22%)	31 (76%)
1: a waste of time / 5: time well spent	-	-	-	9 (22%)	32 (78%)

Evaluation – Effective in reaching the goal

Effective in reaching the goal: Gather experiences of working in the system of regulatory toxicology



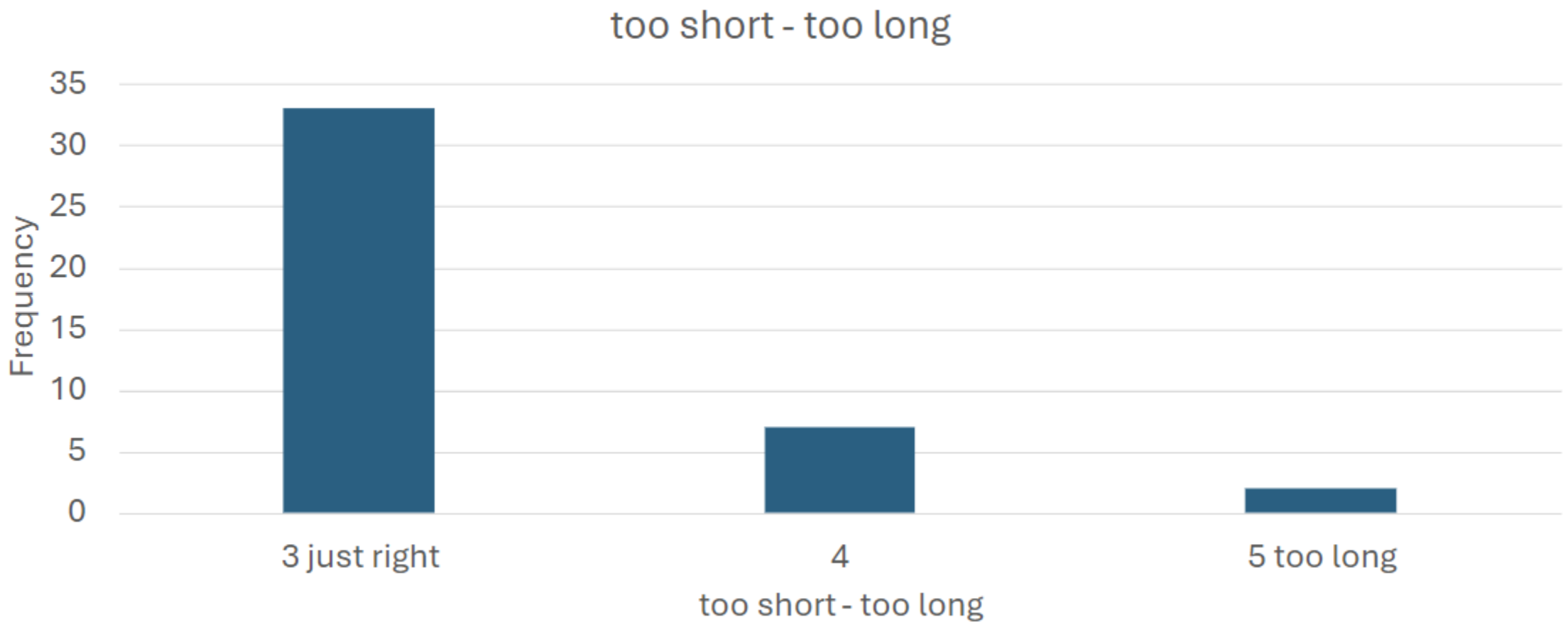
Evaluation – Individual experiences

	1 Strongly disagree	2 Disagree	3 Agree	4 Strongly agree	5 Do not know
I feel that I've gained a lot new and useful insights into other people's views.	-	2 (5%)	13 (31%)	27 (64%)	-
The experiences that I gained in the workshop will impact my work in the future.	-	4 (10%)	16 (38%)	19 (45%)	3 (7%)
The workshop made me aware of my own assumptions and potential preconceptions.	-	3 (7%)	24 (57%)	12 (29%)	3 (7%)
I felt comfortable sharing my own perspectives in the workshop.	1 (2%)	2 (5%)	15 (36%)	22 (52%)	2 (5%)

Evaluation of individual parts

	1 I did not like this at all	2 I somewhat did not like this	3 I liked this somewhat	4 I liked this a lot	5 Do not know
Input presentations	-	1 (2%)	10 (24%)	31 (74%)	-
Small group discussions (anecdotes)	-	1 (2%)	9 (22%)	32 (76%)	-
Large group discussions (fishbowl)	-	5 (12%)	16 (38%)	21 (50%)	-
Prioritisation	-	8 (19%)	14 (33%)	17 (41%)	3 (7%)
Small group discussions (details)	-	4 (9%)	7 (17%)	26 (62%)	5 (12%)
Small group discussions (mapping)	1 (2%)	4 (10%)	9 (21%)	23 (55%)	5 (12%)

Evaluation – Duration



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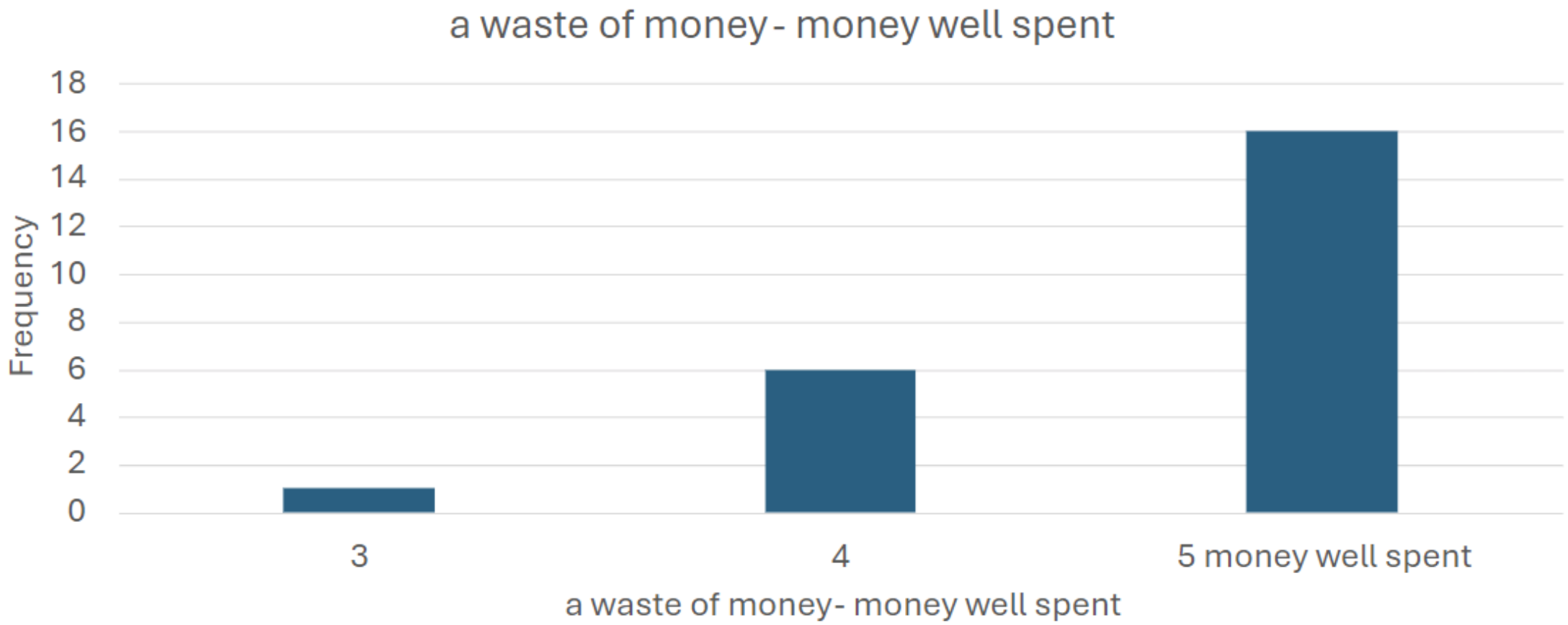
Evaluation of organisation

	☆	☆☆	☆☆☆	☆☆☆☆	☆☆☆☆☆
Comm. Before	1 (2%)	-	-	12 (29%)	29 (69%)
Comm. During	-	-	1 (2%)	8 (19%)	33 (79%)
Oslo	-	-	2 (5%)	3 (7%)	37 (88%)
Venue	-	-	-	2 (5%)	40 (95%)
Venue facilities	-	-	-	5 (12%)	37 (88%)
Coffee breaks	-	1 (2%)	1 (2%)	4 (10%)	36 (86%)
Lunch/dinner at the venue	-	-	-	5 (12%)	37 (88%)
Dinner at the Mexican restaurant	3 (8%)	-	3 (8%)	9 (24%)	22 (60%)
Hotel	-	-	3 (17%)	7 (39%)	8 (44%)
Trip organisation	-	1 (5%)	-	3 (17%)	14 (78%)

Evaluation – Waste of money or not?



CHANGE website and first publication

- VKM CHANGE-website
- Time for CHANGE: system-level interventions for bringing forward the date of effective use of NAMs in regulatory toxicology