



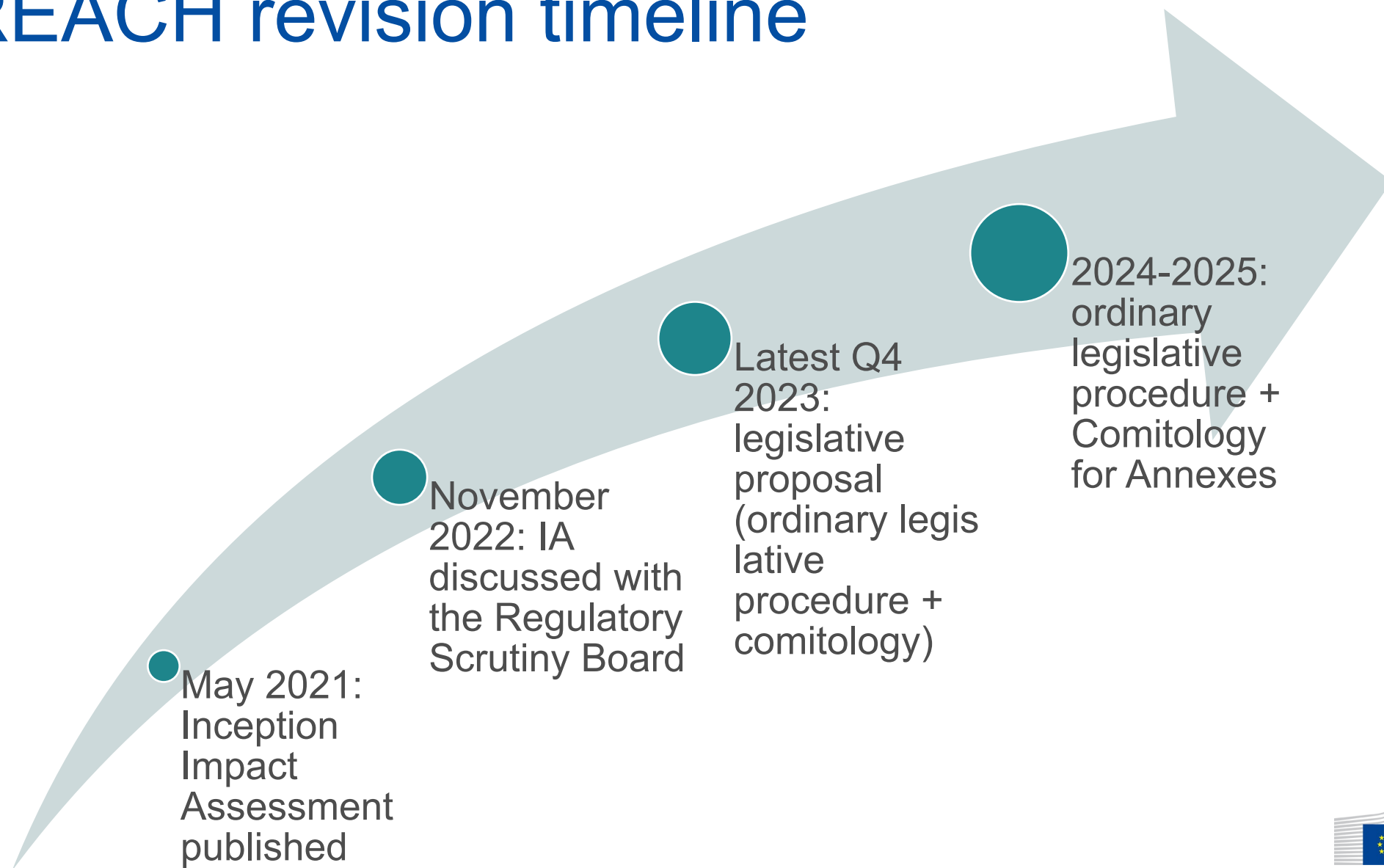
REACH revision

Overview and specific questions for consultation

CARACAL-48 (28 March 2023) AP 4.1

GROW.F1
ENV.B2

REACH revision timeline



REACH revision content (green >> Comitology)

1. Increased **information requirements** for low tonnages/most harmful substances, Chemical Safety Assessment & Report also for 1-10 tonnes
2. Registration of **polymers**
3. **Mixture Allocation Factor (MAF)** to tackle cocktail effect and multi-exposures
4. **Derived Minimal Effect Level (DMEL)**
5. Update **nanofom** provisions, link to 2022 nanomaterial definition (OLP and comitology)
6. Strengthen compliance by **revocation** mechanism and efficient **Evaluation** conditions

REACH revision content

7. Extension of the **generic risk approach** (art. 68(2)) to the most harmful substances with derogations only for **essential uses** (to be defined in a stand-alone horizontal policy document)
8. **Authorisation and restriction reform** to streamline these regulatory tools and reduce the burden on companies and authorities
9. **Audit capacity** together with provisions on organisation and implementation of MSs control systems (Market Surveillance Regulation provisions applied to the whole scope of REACH + complementary provisions)
10. **Access to justice** provisions to better protect citizens from non-compliance with REACH **and considering a compensation mechanism**
11. Strengthen automated **customs controls** of registrations, authorisations, restrictions, enhance risk management, empower OLAF to carry out investigations



REACH revision - Information Requirements

CARACAL-48

28 March 2023

1. Increased **information requirements** for low tonnages/most harmful substances

- Details on the update of information requirements are still under discussion
- The presentation provides an overview of **some of the considerations** for updating the requirements
- Aim is to increase information for low tonnage substances and for most harmful substances including endocrine disruptors
- Need to take cost increase (low tonnages) and proportionality considerations into account
- Reduce the need for animal testing, if possible, by including NAMs or animal-free methods

1. Increased **information requirements** for low tonnages/most harmful substances - Human health / ED

- **New NAM requirements in Annex VII under consideration:**
 - in vitro cytotoxicity (Neutral Red Uptake Assay)
 - toxicokinetics & ADME
 - in chemico protein binding (e.g. fraction unbound in human plasma)
 - in vitro human hepatic clearance (e.g. isolated human hepatocytes)
 - in vitro intracellular bioaccumulation (e.g. in Caco-2 cells)
 - in vitro intestinal absorption (e.g. Caco-2 permeability)
 - ED In vitro mechanistic information (relevant for HH and ENV)
 - Estrogen receptor transactivation assay (OECD TG 455)
 - Androgen receptor transactivation assay (OECD TG 458)
 - H295R steroidogenesis assay (OECD TG 456)
 - Aromatase assay (OPPTS 890.1200)

1. Increased **information requirements** for low tonnages/most harmful substances - Human health

- **Considerations to increase information for low tonnage substance, but limit testing with triggers to substances that raise concerns, e.g. for following tests:**
 - Triggering testing for repeated dose toxicity and screening for reproductive/developmental toxicity (OECD TG 422) for low tonnages?
 - Triggering in vivo tests on endocrine disruption?
- Inter alia, the following options for triggers under discussion:
 - Trigger based on biological half-life predicted from log Kow (>3)
 - In addition, based on in vitro toxicokinetics data (to be generated only after this revision)

Any views on triggers? Other ideas for triggers?

1. Increased **information requirements** for low tonnages/most harmful substances - Environment

- **Replacing short-term fish toxicity test:**
 - In vitro cytotoxicity (OECD TG 249) or fish embryo toxicity (OECD TG 236)

Question: Can we rely on these NAMs/animal-free methods?

- **Move from Annex IX to Annex VII:**
 - Long-term toxicity testing on invertebrates (Daphnia)

1. Increased **information requirements** for low tonnages/most harmful substances - Environment

- **Replacing bioaccumulation in fish (Annex IX) by either**
 - In vitro test OECD TG 319A/B (i.e. intrinsic clearance in rainbow trout hepatocytes) and in vitro–in vivo extrapolation (IVIVE) for estimation of kinetic BCF
 - or*
 - Bioaccumulation in invertebrates (e.g. Hyalella Azteca bioconcentration test)

Question: Should registrants have the choice to use either of the two approaches?

1. Increased information requirements for low tonnages/most harmful substances – endocrine disruptors

- Consideration to base in vivo follow up on weight-of-evidence approach, including for low tonnage substances
- Triggers/waivers under discussion
- **Additional requirements for ED-identification human health:**
 - Uterotrophic Bioassay in Rodents (OECD TG 440)
 - Hershberger Bioassay in Rats (OECD TG 441)
- **Additional requirements for ED-identification environment:**
 - Amphibian Metamorphosis Assay (OECD TG 231)
 - Fish Sexual Development Test (OECD TG 234)
 - Medaka Ext. One-Generation Reproduction Test (OECD TG 240)
 - Larval Amphibian Growth and Development Assay (OECD TG 241)

1. Increased information requirements for low tonnages/most harmful substances - balance

To update to scientific progress and balance the additional requirements at low tonnages and for EDs, inter alia the following are proposed to be deleted:

- acute oral toxicity in rats (Annex VII)
- acute dermal & inhalation toxicity in rats (Annex VIII)
- skin corrosion/irritation (Annex VIII)
- serious eye damage/eye irritation (Annex VIII)
- assessment toxicokinetic behaviour to the extent that can be derived from the relevant available information (Annex VIII)
- further studies beyond the 90-day study (Annex IX column 2)
- pre-natal developmental toxicity study 2nd species (Annex X and trigger in Annex IX)
- long-term repeated toxicity study (≥ 12 months) (Annex X)
- **carcinogenicity study (Annex X) ?**



REACH revision - Registration of polymers

CARACAL-48

28 March 2023

2. Registration of polymers - overview

- **Notification** of all polymers
- **Registration** of polymers requiring registration (PRR)

Associated REACH changes:

- Amendment of relevant articles in the Registration chapter (Article 2, 3, 5, 6, 7, 10, 11, 12, 20, 21....)
 - Addition of a new Annex for requirements applicable to polymers:
 - information to be submitted at notification
 - criteria for identifying polymers requiring registration
 - *placeholder* for criteria for grouping of PRRs or via a guidance
 - *placeholder* for information to be submitted at registration
- (Type 1 or also Type 2&3)

2. Registration of polymers – notification for all

- **Notification - purpose:**
 - map the polymer universe
 - allow ECHA to define grouping criteria
 - allow industry to organize the registration stage of PRRs
- **Notification - information:**
 - limited information on polymers required to identify them, assess if a polymer does or does not need to be registered, and allowing to define grouping criteria. More info for PRR, less for non-PRR.
- **Notification - timing:**
 - earliest 3 years after entry into force for polymers on the market (tbd)
 - before start of marketing for new polymers

2. Registration of polymers – registration of PRR

- **Registration - purpose:**
 - obtain critical hazard information on polymers deemed to be equally hazardous as other substances
- **Registration - information:**
 - different according to molecular weight
 - low MW polymers (Type 1): similar to non-polymeric substances
 - medium & high MW polymers (Type 2&3): very limited requirements (consider ECHA proposal for CASG-polymers)
- **Registration - timing:**
 - 8 years after entry into force for low MW polymers (Type 1)
 - 12 years after entry into force for medium and high MW polymers (Type 2&3)
(options: timing or requirements & timing to be subject to a review)

2. Registration of polymers – PRR criteria

- **Criteria to identify polymers requiring registrations (PRR)**

COM favours the following:

- Polyesters built from a list of ECHA-approved monomers = non-PRR
- **PRR if:**
 - fluorinated polymer
 - cationic polymer
 - polymer with certain Reactive Functional Groups
(same RFG categorisation as in the US and Australia)
 - polymers > 1 000 Da with an oligomer content > 2% of MW <500 Da, > 5% of MW <1 000 Da
 - polymer classified in any of the most severe hazard classes*
 - polymer surface active (< 45 mN/m)
 - polymer suspected to degrade to substance(s) of concern

*Acute Tox. 1 to 4; Muta. 1A, 1B and 2; Carc. 1A, 1B and 2; Repr. 1A, 1B, 2, Lact.; Asp. Tox. 1; Resp. Sens. 1; Skin Sens. 1; STOT SE1 to SE3; STOT RE 1 and 2; Aquatic Acute 1; Aquatic Chronic 1 to 4; ED human health or environment; PBT; PMT.

2. Registration of polymers - precursors

- **Polymeric precursors**

It was still undecided in CASG-polymers if they should require registration.

COM favors that:

- precursors handled under strictly controlled conditions would be exempt
- precursors handled under 'adequate control' (less than SCC) would benefit from limited registration requirements (in analogy to on-site or transported intermediates cf Article 17 or 18)



REACH revision - Mixtures Allocation Factor

CARACAL-48

28 March 2023

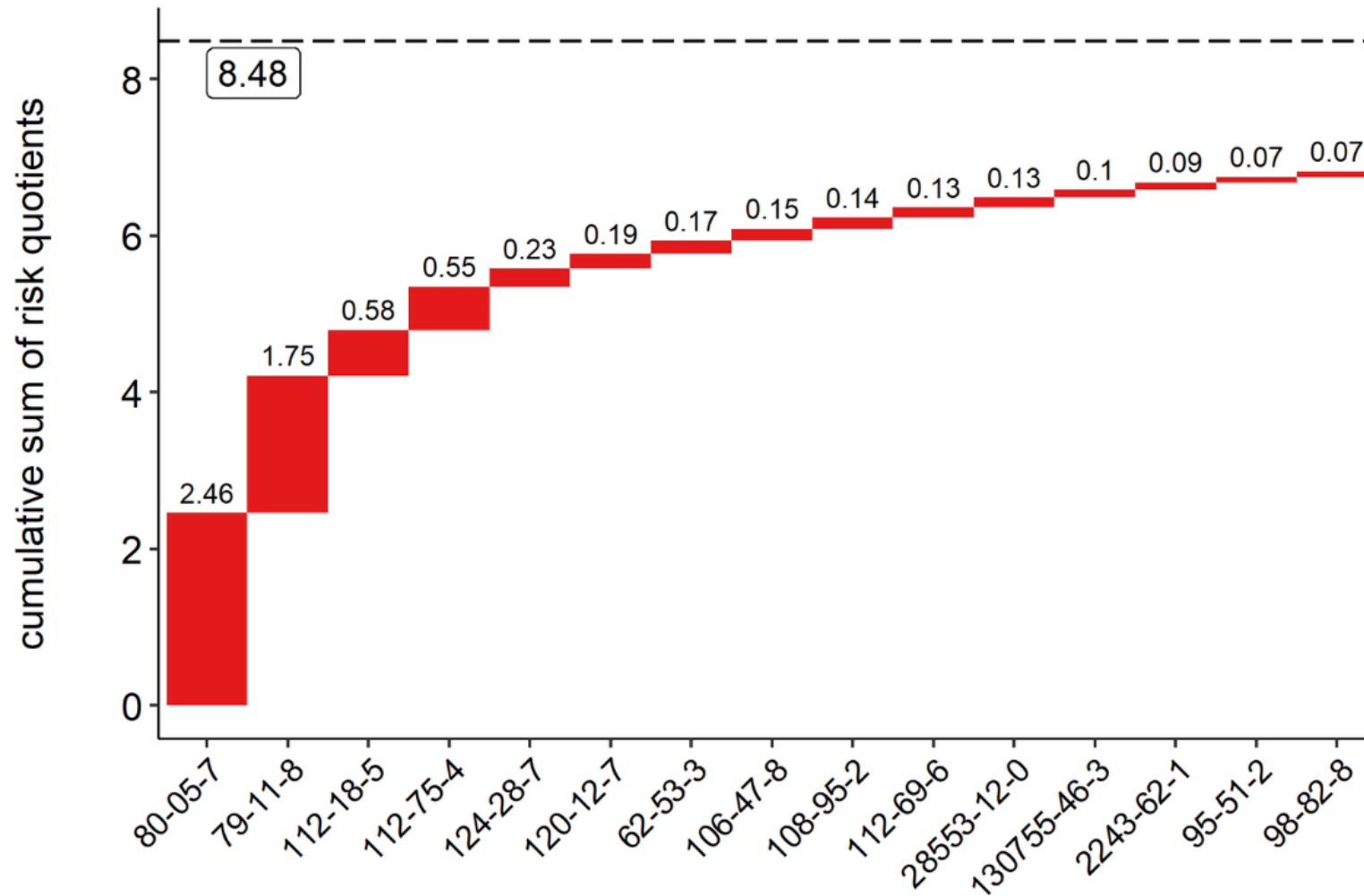
Baseline: Registration of substances

- Manufacturers and importers shall register substances in quantities ≥ 1 tonne/year
- Registrations shall include a Chemical Safety Report (CSR) for substances in quantities ≥ 10 tonnes/year
- For hazardous substances, the CSR shall document that each individual use is safe, i.e. that exposure $\leq$ DNEL or PNEC

Registrants' responsibilities

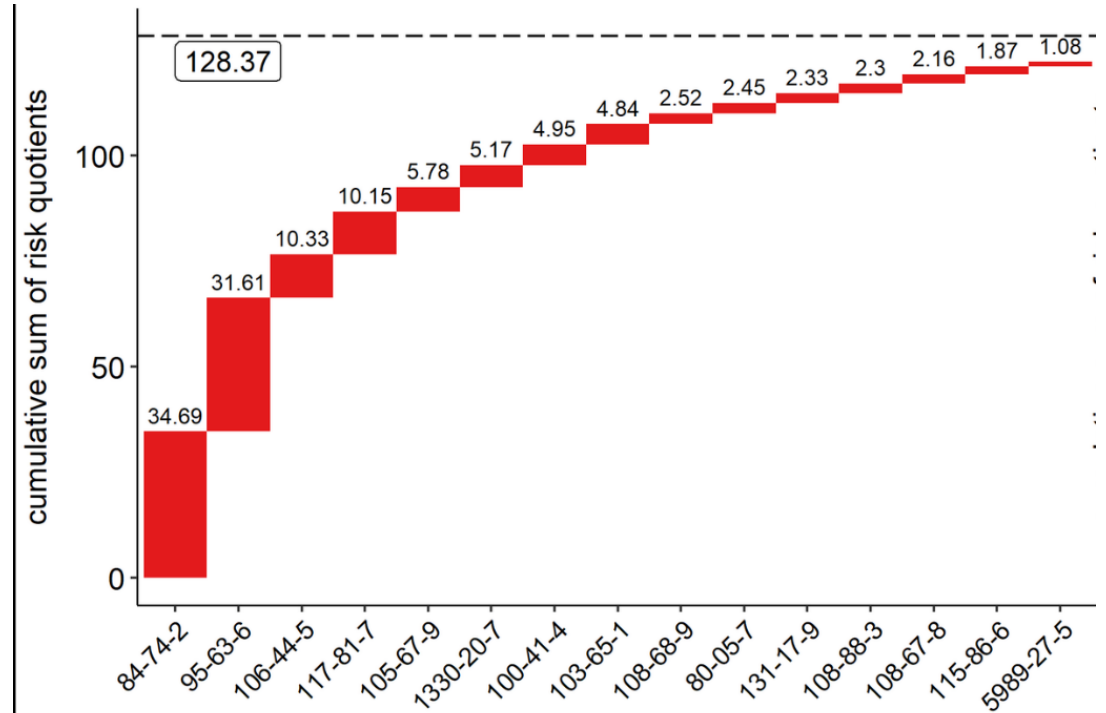
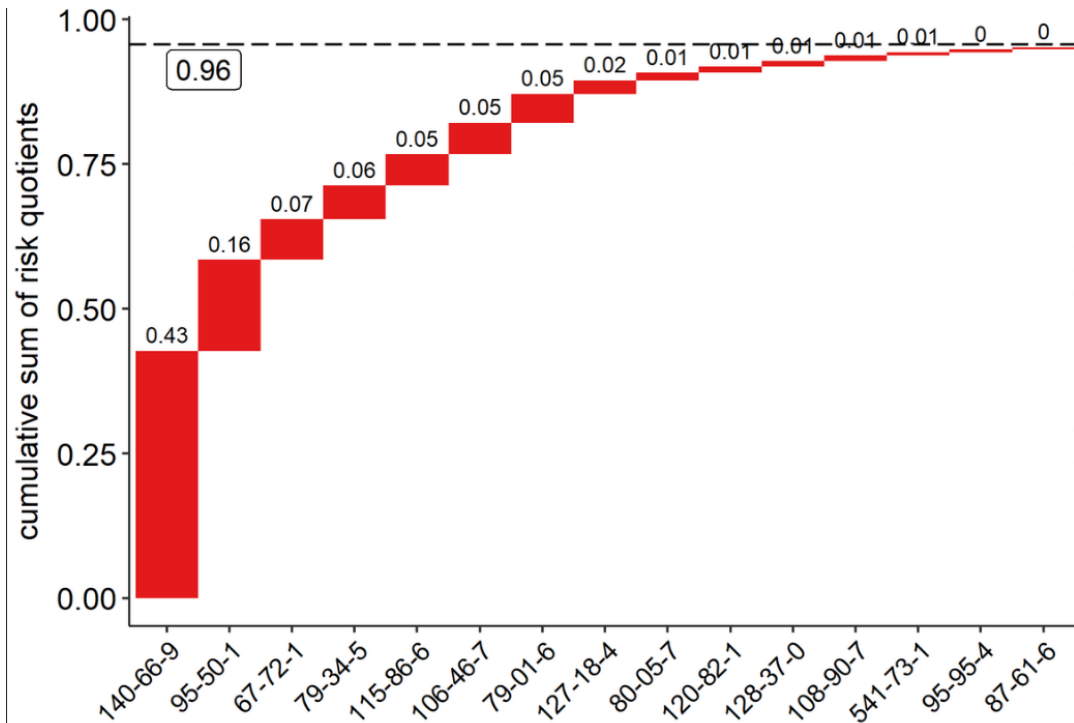
- Individual registrants are responsible for the safe use of their own substances
- Normally, they do not know much about other uses of the same substances registered by competitors
- They do not know how users of their substances, the general population and the environment are exposed to other substances

The problem – modelled exposure data

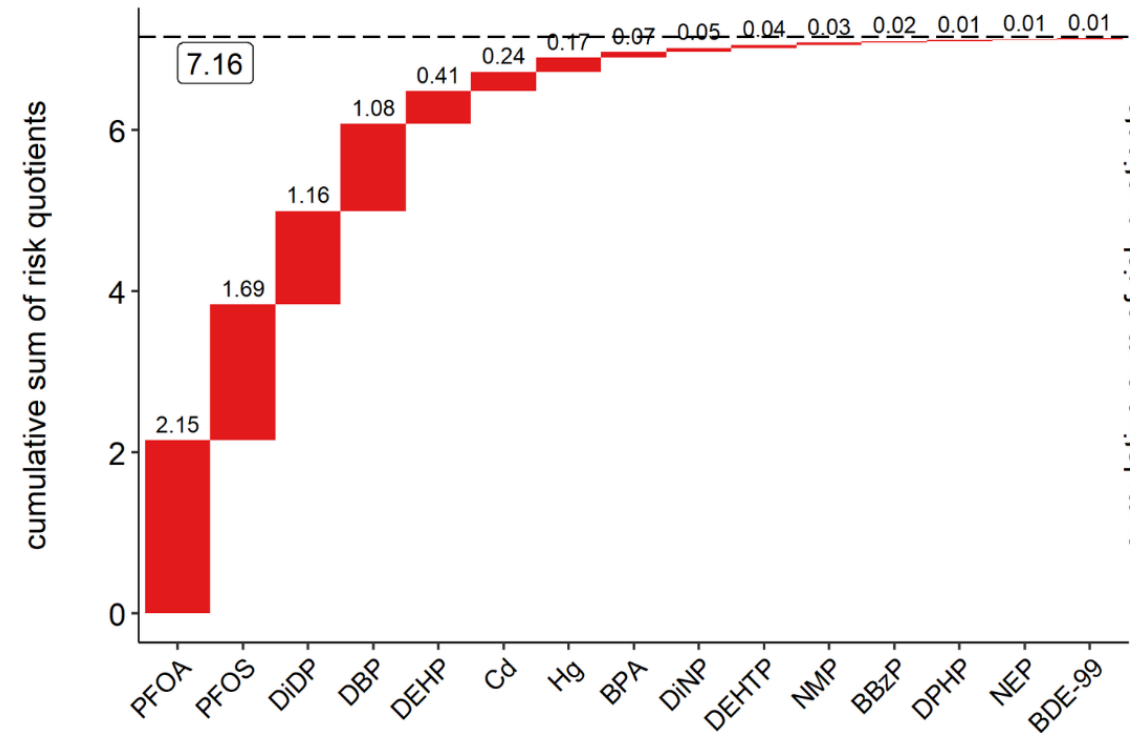
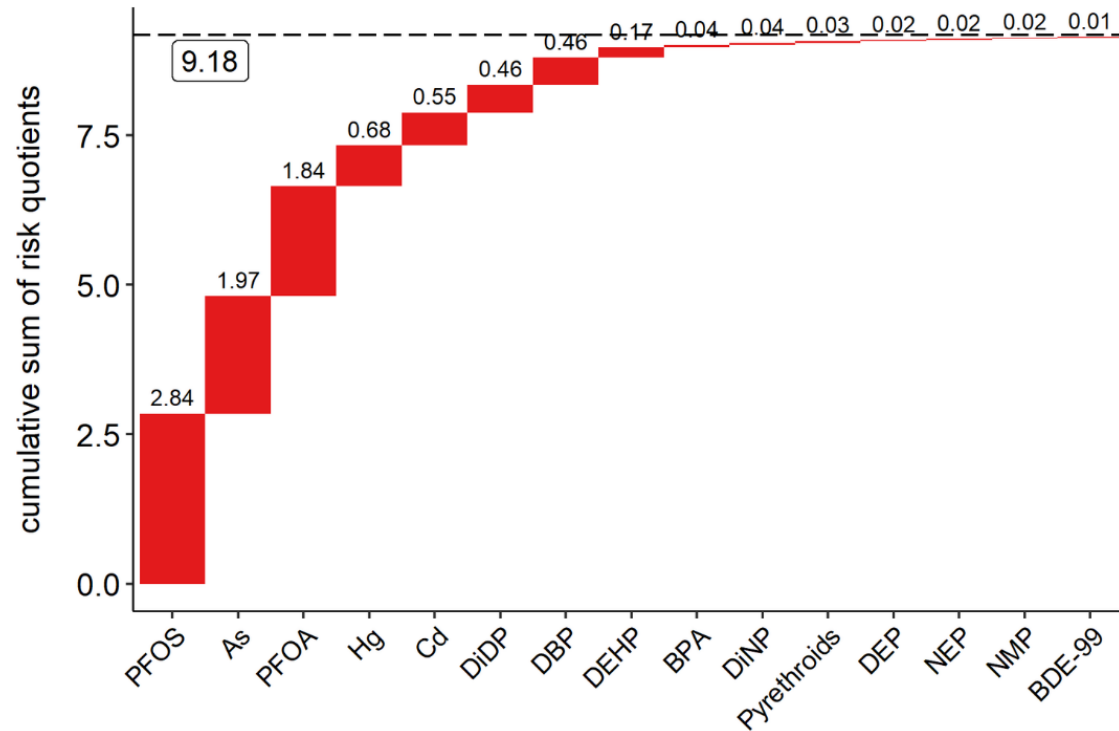


Thomas Backhaus (2023) based on data from van Gils et al. (2020) and Posthuma et al. (2019)

The problem – environmental samples (UK)



The problem – human biomonitoring samples



The problem

- Large database showing cumulative risk levels exceeding a risk characterisation ratio (RCR) of 1 (95th percentiles)
- Many environmental samples, fewer human biomonitoring samples (ethical grounds?)
- “The Scientific Committee* recommends adoption of the mixture assessment concept of dose addition as a pragmatic and precautionary default assumption”

* EFSA Scientific Committee (2019)

What to do?

- Scientifically preferred: Specific risk or safety assessments taking into account all (relevant) substances to which human populations and the environment are exposed
 - Generally not feasible due to lack of data; however, required under the Chemical Agents Directive for occupational risk assessment (but doesn't take into account that workers also have a life outside the workplace)
- Alternative: Risk management approach – Mixtures Allocation Factor (MAF) – when a specific risk assessment is not possible
- MAF should be applied to the RCR ($RCR \leq 1/MAF$)

Which value of MAF?

- All analysed samples show same distribution pattern – log-normal distribution (Pareto)
- Distribution can be described mathematical by the Maximum Cumulative Ratio (MCR)

$$MCR = \frac{\sum RCR}{RCR_{max}}$$

- MCR value between 1 and n (number of substances)

MCR values estimated for various studies

Sample	MCR-90	MCR-95
Deltares modelling	4.1	5.0
UK freshwater monitoring	2.3	2.7
UK groundwater monitoring	1.8	2.1
River Erft	2.0	2.4
Human biomonitoring (JRC)	-	3.3
		3.2
Human biomonitoring (EDs)	1.4	-
Air pollution	2.9	-

Can we use the MCR as MAF?

- Only substances with $RCR > 1/MAF$ will be affected
- Substances will have more or less different use patterns and will have different fate properties
- Humans are behaving and are thus affected differently
- Future distribution of RCR will still be log-normal
- But the distribution of RCR values will be 'flatter' (RCR_{max} is reduced, MCR will increase – how much?)

Which value of MAF?

- Proposal: Use MCR with an extra safety factor of 2 (uncertain whether this is enough)
- Same MAF for humans and environment (similar distribution patterns of RCRs)
- Use 95th percentile MCRs*2 (range 3 – 10)
- Proposed MAF = 5 (uncertainties recognised)

Effect of MAF (=MCR*2) on estimated RCRs

MAF	Estimated Σ RCR (range)
2	3 (1.5-5)
5	1.2 (0.6-2)
10	0.6 (0.3-1)
20	0.3 (0.15-0.5)

Implementation of MAF

- Revise hazard estimate – increase DNEL or PNEC, e.g. more (test) data
- Revise exposure estimate – use higher tier model, use (more) measured data
- Reduce exposure – e.g. introduce (more) Risk Management Measures, improve Operational Conditions
- Stop use(s)

Proposed implementation of MAF

- MAF is risk management tool, proposed value = 5
- Derogation possible if a specific risk assessment is carried out and documented (e.g. workers exposure under CAD)
- Only substances registered at $\geq 1,000$ t/y (covering >99.8% of total tonnage registered)
- Review clause in Article 138

What about non-threshold substances?

- Mainly carcinogens and mutagens, 350-400 registered at $\geq 1,000$ t/y
- Assumed a thorough database would allow establishing Derived Minimal Effect Levels (DMEL) allowing a quantitative risk characterisation for most of these, without new animal tests
- For PBT/vPvBs, requirement to minimise emissions and exposures still apply

Conclusion

- MAF is a risk management tool
- Horizontal MAF = 5
- Apply to $\geq 1,000$ t/y substances
- For non-threshold carcinogens DMELs should be established, but no additional animal tests
- Opt-out based on specific risk assessment
- Review clause in REACH



REACH revision - Nanofom Update

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28 March 2023

5. Nanoform update

- **Update definition of nanoform**
 - Nanoform of a substance = form that is nanomaterial according to definition of nanomaterial in Commission Recommendation 2022/C 229/01
 - 2022/C 229/01 developed for horizontal application across sectors
- **Give unique name, clarify nanoform/set, nanoforms characterization requirements**
 - Responding to implementation experience
- Obligation of **downstream user** producing (transforming into) nanoform not covered by registration could reflect more closely obligation of registrant regarding nanoforms (characterization, information to allow safe use)



REACH revision - Revocation & Evaluation

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28 March 2023

6. Revocation of registration & Evaluation

- **Problem**

- **Lack of compliance of information in registration dossiers**

- **Solution**

- Maintain but improve
 - Support and increase efficiency of existing mechanisms of technical completeness check and dossier but also substance evaluation
 - Introduce revocation mechanism as deterrent of incompliance and support to enforcement
 - 'Clean' registration database of expired dossiers

This is about **legal provisions** of the instruments; **strategy and extent of application** e.g. number of compliance checks has to be dynamic, to be determined on basis of review of joint evaluation Action Plan, and anticipated impact of new registration and information requirements

6. Revocation of registration

- **Revocation mechanism - objective:**
 - empower 'no data-no market' provision in cases of persistent noncompliance or expiry of technical dossier by revoking registration number/access to market
 - **Expiry of technical dossier:**
 - technical dossier should be updated (and subject to TCC) at least every [10] years
 - **All evaluation decisions shall be respected in time and content:**
 - Unjustified delay or insufficient address of request = persistent noncompliance
- **Mechanism**
 - Transparent process; covering special situations (via extension of deadline); appealable
 - Impact: revocation of reg. number, informing national authorities, requires re-registration
 - Expected to work as strong deterrent so eventually not used frequently

6. Evaluation

- **Addressing all evaluation decisions and process**
 - Allowed consideration of addressing objectives for a **group** of substances
 - Once test is requested, it should be implemented or attempt to **adaptation** announced well in advance, leading to corresponding change in deadline
 - Further clarity on how evaluation decisions need to be respected in case of **cease of manufacture or import**
 - During decision making
 - **Commenting** limited to draft decision and observations
 - Change to process/**timing** for efficient work of the Member state Committee
 - Revocation 'stick'

6. Evaluation

- **Testing proposal examination:**
 - reserve mechanism for targeted information generation situations with complex testing strategies, animal testing across all Annexes
- **Compliance check:**
 - announce in advance, after start limit assessment to information in the dossier (new identified existing test as only derogation)
- **Substance evaluation:**
 - Replace CORAP with (simple) registry
 - Explicitly include hazard-based (next to risk-based) approach as possible SEv justification
 - Include ECHA as an evaluating authority



REACH revision - Audit Capacity

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28 March 2023

8. Audit Capacity + provisions for MSs' control systems

- **Empower the Commission to carry out controls of MSs' control systems (REACH and CLP):**

Programmed audits (specific scope) + ad hoc controls in case of serious concern

Combination of proactive and reactive approach

Ensures that all MSs are covered while allowing to focus on the most relevant aspects/ relevant for (groups of) MSs

- Participation of MSs experts in Commission audit team

- **Criteria for MSs official control systems:**

Criteria in Market Surveillance Regulation → applied to the whole scope of REACH obligations

(Now only apply to control of obligations related to placing on the market)

E.g: CAs have necessary control powers, risk based controls

Complemented with other criteria (REACH and CLP) E.g. training

REACH revision

- Improving enforcement: Controls to combat REACH infringements
- Access to justice in case of REACH infringements

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28 March 2023

Customs controls

- **Strengthening customs controls of imported chemicals**
 - Safety at customs controls, including provision of safety data sheets
 - Automated controls of registration requirements
 - Automated controls of authorisation requirements
 - Cooperation for customs enforcement of restrictions and ensuring enforceability

OLAF/online sales/considering access to justice

- **Empowering OLAF to carry out investigations under REACH**
 - Supporting and complementing enforcement activities of Member States
 - Empowering the Commission to carry out inspections in close cooperation with national authorities
 - Empowering the Commission to collect information through interviews and other means, with the appropriate procedural guarantees of the inspected persons
- **Providing for a responsible economic actor in the case of online sales**
 - Requiring a supplier established in the Union, for sales from third countries shipped directly to consumers
 - Supplier acting in the course of a professional or industrial activity, to be responsible for fulfilling REACH requirements
- **Considering access to justice for better protection of citizens against non-compliance**
 - Providing for the possibility to submit concerns to competent authorities, for investigation of infringements
 - Considering access of citizens to judicial or administrative review procedures and possibly a compensation mechanism



Changes of REACH Annexes

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28 March 2023

REACH Annex changes

- Annex I amendments to introduce MAF, incl. DMELs for non-threshold substances
- Annexes VI – X amendments to reflect changed information requirements, nano updates
- Annex XI amendments to further encourage use of NAMs and increase clarity
- New Annex XVIII for polymer requirements
-?



REACH revision - Reform of Authorisation and Restrictions

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28 March 2023

Reform of Authorisation and Restrictions

- **Earlier information on use, exposure and alternatives**
 - For all substances in the registration dossier
 - For the most harmful substances more details in registration dossier
 - For substances of very high concern new notification system for downstream users
 - Further information on request where e.g. restriction dossier is being prepared

Reform of Authorisation and Restrictions

- **Keep Titles VII and VIII separate but adapt rules for both to simplify processes**
 - By allowing the Commission to upfront exclude essential uses from scope of authorisation requirement
 - Adapt process and criteria for derogations under restrictions
 - Increased use of broad restrictions (GRA, grouped restrictions)
 - Limiting applicant by applicant authorisation
 - Strengthen the role of substitution plans
 - Details still under discussion

Reform of Authorisation and Restrictions

- **Implement the essential use concept**
 - Derogations from generic restrictions only for essential uses
- Additional/complementary criterion to existing criteria for derogations from specific restrictions and Annex XIV obligations
 - Simplification for clearly essential and clearly non-essential uses through upfront scope exclusions/not allowing derogations resp.
 - Details on process for less clear cases still under discussion

Thank you



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