# Managing mixture risk

Policy needs and ongoing developments

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Unintentional mixtures of chemicals that result from emissions from different sources and exposure routes

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Unintentional mixtures of chemicals that result from emissions from different sources and exposure routes

# What is the state of play?

- EU chemicals control is complex; Large number of substances, several laws, different authorities, EU and national levels
- Legislation focus on single chemicals but the science is clear: The risk increases when mixtures are considered
- So, current legislation systematically understimates environmental and health risks
- Methods for assessing mixtures are available, but legislation lags behind


EUROPEAN COMMISSION

Brussels, 14.10.2020
COM(2020) 667 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Chemicals Strategy for Sustainability
Towards a Toxic-Free Environment

{SWD(2020) 225 final} - {SWD(2020) 247 final} - {SWD(2020) 248 final} - {SWD(2020) 249 final} - {SWD(2020) 250 final} - {SWD(2020) 251 final}


# Future chemical risk management

Accounting for combination effects and assessing chemicals in groups

SOU 2019:45

Full report available (in both english and swedish):
https://www.government.se/legal-documents/2019/11/sou-201945/

Inquiry's proposal:

# Establish consistent requirements for mixture risk assessments in all pieces of chemical legislation

**Current situation**

- EU chemical legislation focuses on single chemicals and is highly fragmented.
- Most of the numerous pieces of legislation do not include any clear requirement for assessing and managing mixture risks

**Why is this action important?**

- Without clear legal requirements, mixture risk assessment cannot be expected to occur

Inquiry's proposal:

# Establish cross-cutting European legislation on chemical pollution with a focus on mixture risks

**Current situation**

- Rules are organized into separate legislations along commercial uses, and not along likely co-exposure patterns

**Why is this action important?**

- Complex unintentional mixtures cannot be fully evaluated and managed by sectorial pieces of legislation

Inquiry's proposal:

# Establish a database on use and emissions of chemicals

**Current situation**

- Current exposure data are scattered and insufficient to address complex mixtures

**Why is this action important?**

- Without sufficient data on use and emissions, mixture risk assessment is not possible
- Data compilation facilitates assessments across legislations

Inquiry's proposal:

# Establish a research program on real-life exposure patterns to chemical mixtures

**Current situation**

- Little is known about typical co-exposure patterns and so called "risk-drivers"

**Why is this action important?**

The research will support:

i. development of modelling approaches for mixture exposure assessment, and

ii. the identification of mixtures of regulatory concern

Inquiry's proposal:

# Introduce an allocation factor of 10% to account for the risk of chemical mixtures

**Current situation**

- Legislation rests on the (unreasonable) assumption that each chemical is emitted into its own pristine environment
- As a consequence, real-world risks are systematically underestimated

**Why is this action important?**

- This is a resource efficient and pragmatic way to manage risks with unknown mixtures

An allocation factor is mathematically the same as applying an additional mixture assessment factor (MAF)

# Chemicals Strategy for Sustainability (CSS) Towards a Toxic-free Environment

- A new long-term vision for the EU's chemical policy

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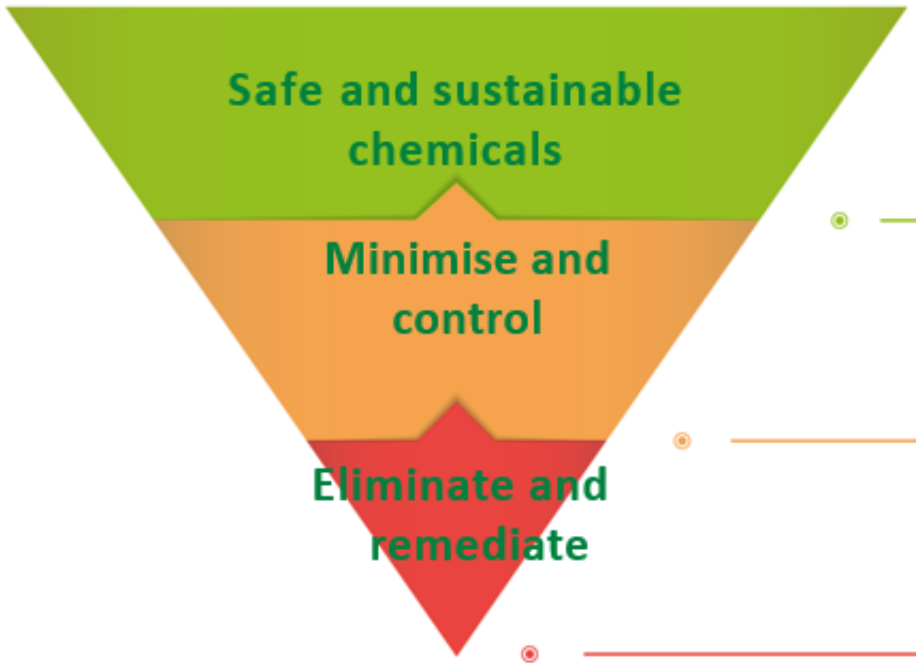



## *Protect health and the environment*

Use of safe chemicals while preventing harm to humans and the environment by avoiding substances of concern for non essential uses

Minimise exposure of humans and environment to substances hazardous to health and the environment, through risk management measures and full information to users of chemicals

Eliminate as far as possible substances of concern in waste and secondary raw material and restore human health and environment to a good quality status

## *Encourage innovation*

Promote the development of safe and sustainable chemicals and materials, clean production processes and technologies, innovative tools for testing and risk assessments

Promote modern and smart production processes, safe and sustainable uses and business models, chemicals as a service, IT solutions for tracking of chemicals

Promote safe and clean recycling solutions including chemical recycling, waste management technologies, decontamination solutions

# Annex 1 to the strategy

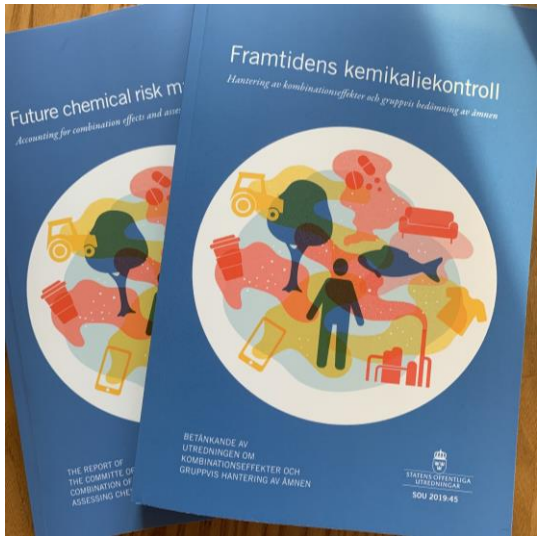
- Contains 56 action points (and time table)
- The Commission, the Parliament and Member States seem committed
- Implementation is key!

# Annex I includes actions for risk management of mixtures

1. Assess how to best introduce in REACH **a mixture assessment factor**, or factors

2. **Introduce or reinforce provisions to take account of combination effects in other legislations**;
   water, food contact materials, food additives, toys,
   detergents, cosmetics

Also proposed in ➡



# Some key questions

- Appropriate size of a MAF?
- One or more MAF(s)?
- Where in REACH should it be applied?
- Consequences for, and interactions with, other legislations?
- Impact assessment for the selected options (economic, social and environmental)

# Science to define an appropriate size of a MAF

**Proposed size of MAF**

- Ranges from 3 to 100..

# Science to define the size of MAF

**Uncertainties**

- What is the “carrying capacity”?
- Exposure data are uncertain
- Temporal and spatial dynamics not yet described (what is a reasonable worst-case scenario?)
- Effect data are uncertain for many substances
- We assume Concentration Addition
- Synergies and antagonism are not accounted for (probably not very significant)
- Only a small part of the substances included in each study
- PPP, BPR and pharma are excluded (not in the current scope)

# Science to define the size of MAF

**Different exposure scenarios**

- *Rivers* hoover up chemicals from many uses
- Less chemicals in *terrestrial ecosystems* and *groundwater*
- Chemical complexity in the *human body* might be lower (in terms of number of chemicals)?

# Science to define the size of MAF

**Options**

- Focus on so called “risk drivers” = High MAF that affect a few chemicals
- Consider full complexity = low MAF affecting more chemicals
- Regardless: the carrying capacity should not be exceeded!

# Time-line for decisions

- Expect a decision in 2022 (?)
- There is a group of consultants assigned to do the analyses
- One work-shop has been arranged (in November)
- Targeted consultations are ongoing
- 2022 and 2023 will be busy years..

**Thank you!**

STATE OF THE IMPLEMENTATION OF THE ACTIONS ANNOUNCED UNDER THE CHEMICALS STRATEGY

| N | Action | Indicative timing | Status | Deliverable |
|---|---|---|---|---|
| 1 | Set up a high level roundtable with the purpose of promoting efficiency and effectiveness of chemicals legislation, boosting development and uptake of innovative safe and sustainable chemicals, and monitoring the impact of the Strategy's actions. | As of 2021 | Roundtable set up, members selected, 1st meeting on 5 May 2020, 2nd on 25 November, 3rd in Spring 2022 | Around 2 meetings per year, joint reports from the Roundtable on specific topics |
| **2.1 Innovating for safe and sustainable EU chemicals** | | | | |
| 2 | Develop EU safe and sustainable-by-design criteria for chemicals | 2022 | Mapping study on existing frameworks published, followed by Stakeholder Survey launched in June 2021. Ongoing technical work by EU services for criteria definition and first case studies. 2nd stakeholder workshop planned for March 2022. | Commission Staff Working Document (to be confirmed) |
| | Establish an EU-wide safe and | | Under the current WP 2021/2022 in Cluster 4 a Coordination and Support Action aims to establish an EU led SSbD international | Coordination and |

https://ec.europa.eu/environment/system/files/2021-11/Table_implementation_CSS_actions.pdf