GERMAN FEDERAL INSTITUTE FOR RISK ASSESSMENT

BfR
Bundesinstitut für Risikobewertung

Views and current work at the BfR with respect to the Chemicals Strategy for Sustainability (CSS)

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Activities of the BfR in the field of EU chemicals regulation

BfR provides risk assessments for

- REACH, CLP, PPPR, BPR, consumer products, cosmetics, food additives/contaminants, FCM, tobacco, tattoos …

Mandate of the BfR

- Human health **hazard characterisation**
- **Risk assessment** for **consumers**
- Provide **counsel** to policy makers (ministries, parliament)
- Engage for **3R** principles
- **NRLs** to support monitoring/enforcement
- **Research** related to the above issues
- **Independent** with respect to its scientific assessments

Manifold international co-operations with respect to method development

- EFSA, ECHA, OECD, WHO, UN, ANSES, DTU …

View on the implementation process of the Chemicals Strategy for Sustainability (CSS)

So far, the CSS mostly relies on input from COM services

- MS risk assessment agencies only marginally involved yet
- Public consultations on a handful of very general roadmaps only
- „High-level roundtable“: necessary, but MS practically not involved (only Council presidency), not a forum for detailed scientific discussions

Long-term research projects initiated under Horizon 2020/Europe

- But time-scale does not match that of regulatory actions taken

“Inception Impact Assessments”

- Important aspects not yet addressed

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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}

Many and complex scientific issues…
Discussions should involve MS agencies
who do the groundwork and have decades of experience in regulatory risk assessment!

Views on fundamental issues related to the CSS from the perspective of risk assessment

Overall narrative („restore human health and the environment to a good quality status“)?

- We can always do better…but is there an imminent need for drastic action?
- Is the current system both, ineffective and inefficient?
- E.g.: are vulnerable/sensitive sub-populations not sufficiently protected?

„Generic approach to risk management“ as default approach for consumer products?

- Drastic move away from risk- towards hazard-based regulation!
- Is it necessary? Or promising?

Combination effects/Mixture Assessment Factor (MAF)?

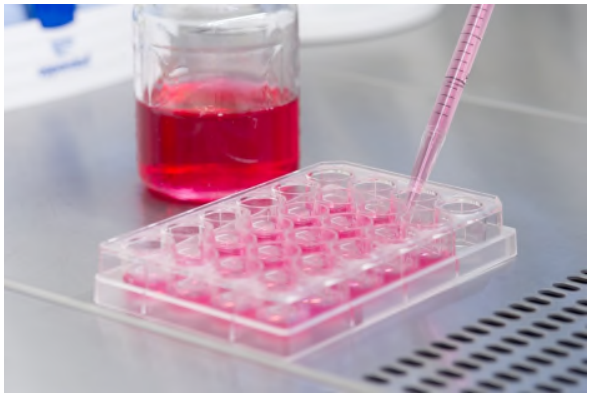
- What do we know about the dimension of the problem from the human health perspective?

Impact on sectorial regulations, „One Substance, One Assessment“ (OSOA)…?

Endocrine Disruptors…?

Engagement with respect to research related to the CSS

BfR engages in several Horizon2020/Horizon Europe activities, e.g. …



RISKHUNT3R

- NAM-oriented project to promote **Next Generation Risk Assessment**
- BfR will provide **experimental work** and engage in **regulatory advisory board**

Panoramix

- Analysis of **potential risks from real-life mixture samples** (Odense child cohort) by analytical multi-method, fractionation, and *in vitro* testing
- BfR will provide **experimental NAM** work as well as develop **case studies** to elaborate on regulatory learnings, e.g. on the need for (and potential size of) a **MAF**

Partnership for the Risk Assessment of Chemicals (PARC)

- Will shape the methodological landscape of **chemical risk assessment in Europe for the next decade**
- BfR active in WP 5 (**hazard assessment**) and WP2 (**knowledge management and uptake into policy**)

Summary

- **CSS supported** in terms of continuous adaptation to state of science and improving efficiency
- But the **current system** of chemicals regulation overall is **effective in safeguarding public health**.
- Communication should not belittle this. We also should **not amplify unjustified concerns**.
- Principal **move from risk- to hazard-based** regulation (generic approach to risk management, MAF)?
- For HH sector: **side-stepping the GHS** when revising CLP?
- Impact on/consistency with **non-REACH regulatory frameworks** (e.g. PPPR) not yet sufficiently considered
- BfR engages in related **research activities** – but results will only become available after implementation of CSS!

CSS tackles complex scientific issues and risk assessment. MS (and EU agency) risk assessment experts from all chemical regulatory frameworks urgently need to be involved in the discussions!

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Thank you for your attention

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