

Chemical Disinfection and Biocidal Product Regulation from the EU perspective

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the plus of pure performance

scope of Biocidal Product Regulation (BPR)

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BPD

Biocidal Products Directive 98/8/EC



BPR

Biocidal Products Regulation 528/2012/EU

in force since September 1st, 2013

scope of BPR

- high level of protection of both human and animal health and the environment
- harmonized market access for & use of biocidal products







the focus has shifted...

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BPR authorization process

...a 2-step procedure

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evaluation of active substances

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...to be completed until December 31st 2024



product authorization process

...a time consuming procedure

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step 2

- biocidal product authorization
- possible on national or Union level



e.g. Union authorization dossier evaluation COM submission BPC prepreparation Implementing by e.g. submission opinion schülke -} Regulation Saua: approx. 2 years up to 3 years

product authorization process

...additional regulatory challenges

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harmonized classification by Risk Assessment Committee (RAC) ?

- up to now no CLH dossiers was submitted
- classification as **CMR** is proposed due to human cancer studies
- \rightarrow misuse of alcoholic beverages chronic oral consumption



Carc. 1A or 1B H350 May cause cancer

- Muta. 1B H340 May cause genetic defects
- Repr. 1A H360FD May damage fertility or the unborn child
- Lact. H362 May cause harm to breast-fed children

legal CLP classification is obligatory for <u>all</u> biocidal uses

- \rightarrow classification is independent from the exposure route / risk
- \rightarrow alcoholic beverages are exempted (foodstuffs)

draft label of a surface disinfectant ...with 30 % ethanol

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today

signal word: WARNING H226: Flammable liquid and vapour. H319: Causes serious eye irritation.

user acceptance = 0 %

future ?



signal word: DANGER H226: Flammable liquid and vapour. H319: Causes serious eye irritation. H340: May cause genetic defects. H350: May cause cancer. H360FD: May damage fertility or the unborn child. H362: May cause harm to breast-fed children

draft label of a hand disinfectant ...with 80 % ethanol

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signal word: DANGER H225: Highly flammable liquid and vapour.

H319: Causes serious eye irritation.

user acceptance = 0 %

future ?



signal word: DANGER

H225: Highly flammable liquid and vapour.

- H319: Causes serious eye irritation.
- H340: May cause genetic defects.
- H350: May cause cancer.
- H360: May damage fertility or the unborn child.
- H362: May cause harm to breast-fed children

costs & fees

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active substance approval

data / studies	100-3000 K€
dossier preparation	50-200 K€
ECHA fee	>120 K€
eCA fee	50-400 K€



biocidal product authorization (Union authorization)

data / studies50-100 K€dossier preparation100-200 K€ECHA fee80 T€ (BP), 150 K€ (BPF)eCA fee~60 T€ (BP), ~100 K€ (BPF)

290-550 K€

lifecycle

annual fee renewal fee

biocidal product family

...similar formulations

biocidal product family



single biocidal product



biocidal product family - a group of biocidal products having

- same actives
- similar uses
- similar composition within specified variations
- similar levels of risk and efficacy
- Frequently used as a tool to reduce BPR costs
- authorization of similar kind of disinfectants

impact of BPR on the medical sector

... is there still room for innovations?

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less actives



NO support for political reasons

- shift to more candidates for substitution
- > non-risk related classification \rightarrow NO user acceptance
- major obstacle for innovations

less applications / formulations





- NO solutions for niche applications
- Iong term process

increasing costs





- study costs
- dossier costs
- evaluation fees
- annual fees

BPR & innovations

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PROBLEMS

- major investment (high costs/fees)
- uncertainty
 - political will to further restrict diversity of active substances
 - o connection of BPR & CLP
 - o non-approval of AS
- RA of biocides does not take the prevention of infections into account

CONSEQUENCES

- limited number of companies driving innovations (big market players ONLY)
- significantly less R&D on novel active substances
- future innnovations/R&D will rather focus on novel formulations/coformulants to enhance the perfomance of the product



discussion

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- A broad variety of biocidal products (disinfectants) are more than ever essential for infection prevention -> protection of human health
- risk / benefit assessment is missing
- risk assessments is based on worst case scenarios (with a focus on the environment)
- > non-risk related labeling & classification leads to minor user acceptance
- > BPR makes INNOVATIONS a high-risk business for industry

How to assure the availability of a sufficient amount of biocidal products in the future ?



BPR - Positive and Negative Aspects from Industrie's View COM/VCI Meeting on 22. January 2018 in Dortmund



VCI's View

Active substances and biocidal products are very important to maintain the modern standards in hygiene and safety. They must be available in future, too.

- Under BPR active substances and products are assessed and evaluated carefully. The real risk should be taken into accound and not just the classification.
- Holistic approach to avoid the loss of AS one by one.
- Consideration of use: The minor in use of biocides is contradictory to other targets as health and climate protection.
 - Use of renewable raw materials
 - Reduction of systems containing solvent
 - Infection prevention
 - Waste avoidance

