Harmonised EU wide BPR enforcement



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About myself

- Legal background: public law, environmental law
- Lawyer (barrister) legal counsel to the BE ministry of Public Health, Food Chaine Safety and Environment (more than 20 years now) advisor to the minister of state reform
- Deputy-major (alderman) in my municipality for the last 12 years (finally over now ...)
- Full time legal counsel to the biocides unit and indoor air quality unit / legal coordinator for product standards/chemicals-policies (also ratification procedures for international treaties)
- Inspector (on-desk inspections) member ECHA Forum BPR-Subgroup
- Since 2020: Vice Chair ECHA Forum BPR-Subgroup / Chair WG Training for trainers
- Since 2023 Chair ECHA Forum BPR-subgroup / member WG BEF





Enforcement EU law = competence of the MS

- Every regulation/directive states: 'MS shall provide sanctions that are effective, dissuasive and proportional"
- Different enforcement systems, inspection instruments, sanctions, ...
- However: EU environmental criminal law (< directive 2008/99 now new directive 2024/1203) on criminal sanctions for some environmental crimes (ao. biocides reach related)
- More harmonization in criminal sanctions (but complicated in transposition in national law)
- Market surveillance regulation 2019/2010 (e.g. corrective measures, e-commerce, "mystery shopping", ...)
- Tendence to (more) harmonized enforcement and sanctions in the EU
- But still differences in national enforcement approach





Transitional period of the BPR

- Important issue in enforcement for biocides
- Art. 89 (2) BPR: MS may apply national system up to 3 years after approval of last active substance of the biocidal product
- Which law to apply? National system? BPR?
- Need to finalise work program review active substances
 - only then: full harmonization and BPR applies fully,
 - until then: mixed both BPR and national law





Transitionnal period of the BPR

Legal scheme which law to apply:

- Active substance(s) approved at EU level => BPR
- Active substance(s) not-approved at EU level or « no longer supported » or not in the review programme => BPR
- Active substances in the review programme, but not approved yet at EU level => national law (4 april 2019 RD)
- Exception : art. 89 (2) BPR = national law





EU harmonized biocides enforcement

- Despite different national enforcement systems => EU wide harmonized biocides enforcement policy on field
- **ECHA FORUM BPR-Subgroup** => BEF-projects Biocides-en-force (// REACH-en-force => REF)
- The BPR-Subgroup (BPR-S): composed of one appointed member from each EU Member State, Norway, Iceland, Liechtenstein and Switzerland. Members are appointed for a period of three years (renewable). Possibility to appoint an alternate BPR Member
- WG BEF within BPR-S (chair : Jenny Karlson, SE)





EU harmonized biocides enforcement

- So far: BEF-1 (treated articles), BEF-2 (approved and non-approved substances), BEF-3 (SPC)
- Every EU MS participating national coordinator, assistance from ECHA, WG
- Project over 3 years :
 - **preparatory** phase (manual for inspectors, delivering training, ...)
 - inspection phase
 - **reporting** phase: report, conclusions, recommendations, practical guidelines for inspectors
- As we speak: inspection phase BEF-3 on SPC ongoing: BPR Enforcement project on controlling the Summary of Product Characteristics for biocides and elements of the Safety Data Sheet
- Forum enforcement projects ECHA





- Less than 2.5 % of the products contained an illegal active substance
- Several MSs reported on articles that were marketed with biocidal claims but were found during inspections not to be treated with a biocidal product

"The biocidal claim was indeed added along the supply chain as some companies seemed to consider it as beneficial in the marketing of the product.

Some companies chose to remove the biocidal claim when inspected to avoid having to comply with the biocidal legislation. This leads to unmonitored TAs on the market, making inspections more difficult (not declared TAs). This situation also makes it more difficult for consumers to make conscious choices when shopping."





Recommendations BEF-1

- "Industry needs to increase the knowledge and raise awareness about the responsibilities on treated articles
- "Member states should continue providing trainings and information campaigns for both NEAs and industry, aiming at improving knowledge about the legal obligations for TAs
- The BEF-1 was the first enforcement project of the BPRS, and it was focused on easily identifiable TAs in the EU market. A follow-up project under the umbrella of the BPRS could also cover unmonitored TAs, that are not simple to identify in the EU market. In this light, it would be crucial for the NEAs to perform more chemical analysis on TAs





Only 79% of inspected 'EU biocidal products' authorized

"high costs for biocidal product authorisations, together with the relevant efforts for companies to comply with biocides legislations. The coexistence of the BPR and transitional authorisations also creates unclarity."

 78% of the inspected biocidal products were available on the market under national transitional measures.

"ensuring a swift progress of the review programme for active substances (leading to their approval/non-approval) is crucial for a safer market."

 BEF-2 showed a good level of compliance with reference to national language requirements on labels





Advertising: 11% of advertisement inspected concerning 'EU biocidal products' was assessed as misleading

"identifies a serious situation and confirms the general tendency for actors involved in supply chains in using attention-grabbing elements and terms in order to promote sales of biocidal products"

- In all, 18% of the inspected biocidal products: considered non-compliant presenting 'major deficiencies' with reference to authorisations, active substances, labelling and advertisement
 - Most non-compliant biocidal products belonged to product types 1, 2, 18 and 19





- Different enforcement measures were taken by the National Enforcement Authorities concerning non-compliant biocidal products in BEF-2
- Enforcement actions varied from verbal advices to criminal prosecutions





Recommendations BEF-2

- "Industry should increase their level of knowledge and awareness about the legal responsibilities in making available biocidal products on the EU market. The high number of biocidal products with deficiencies is a crucial aspect of the biocides market, and industry are the key actors to ensure improvements"
- "Member states should continue providing training and information campaigns to both National Enforcement Authorities and industry, aiming at improving their knowledge on BPR requirements"





Recommendations BEF-2

- "The BPRS highlighted the importance for the Member State Competent Authorities as main actors of the review, and the European Commission as the guardian of the treaties, as well as the industry as the actor responsible for information on active substances, to take appropriate actions to conclude the review programme of active substances"
- "The current coexistence of the BPR and transitional authorisations creates unclarity and difficulties in harmonising enforcement actions in EU and results in a lack of level playing field for companies."



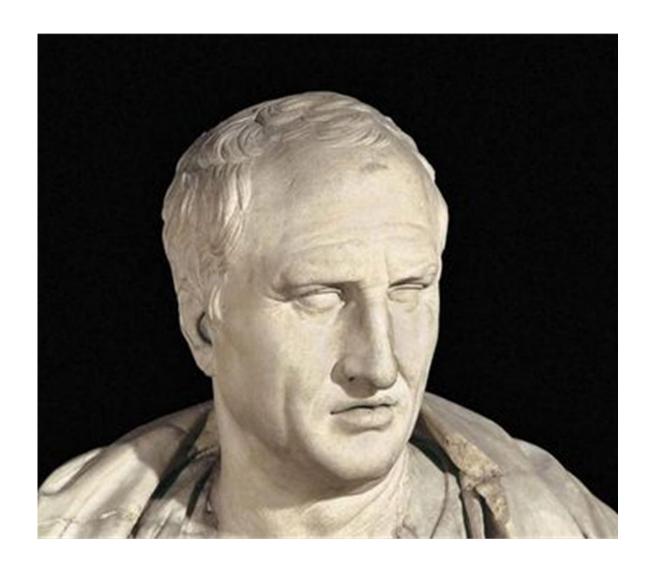


Other EU wide harmonised biocides enforcement within BPR-S

- yearly training (2025 training on fold-out labeling)
- Practical Issues
- Open sessions of ECHA Forum with stakeholders
- share data, good practices
- exchange experiences
- advice on enforceability (BPC)
- => more and more EU wide harmonized biocides enforcement





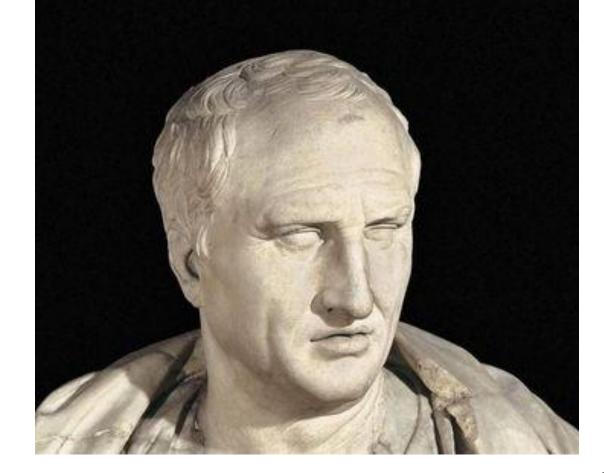






Lex est rectio praeceptio pravique depulsio

(Marcus Tullius Cicero)







Antwerp dialogue on enforcement

- European Industrial Deal to complement the Green Deal ("the Antwerp Declaration") - more than 1200 associations signed to date
- "Legislation is as good as its enforcement"
- key takeaways from the Antwerp Dialogue on enforcement reported by Cefic at last Open Session :
 - Political leaders need to make enforcement a priority
 - Harmonise and coordinate MS enforcement and control
 - Make enforceability as part of law making
 - More financial resources for enforcement
 - More pro-active approach to e-commerce





Conclusions

- Tendence to (more) harmonized biocides enforcement and sanctions in the EU
- Despite call for deregulation : need for more (clearer) regulation/harmonization
- Need to conclude the EU work program review active substances





Questions?

And answers, *maybe* ...

Thank you for your attention!
Go raibh maith agat as do aire!

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