The situation of formaldehyde releasers and the need for a holistic approach on in-can preservatives (PT 6)

FABI INFORMATION DAY – USES AND BENEFITS OF BIOCIDAL ACTIVES

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ABOUT CEPE

About CEPE

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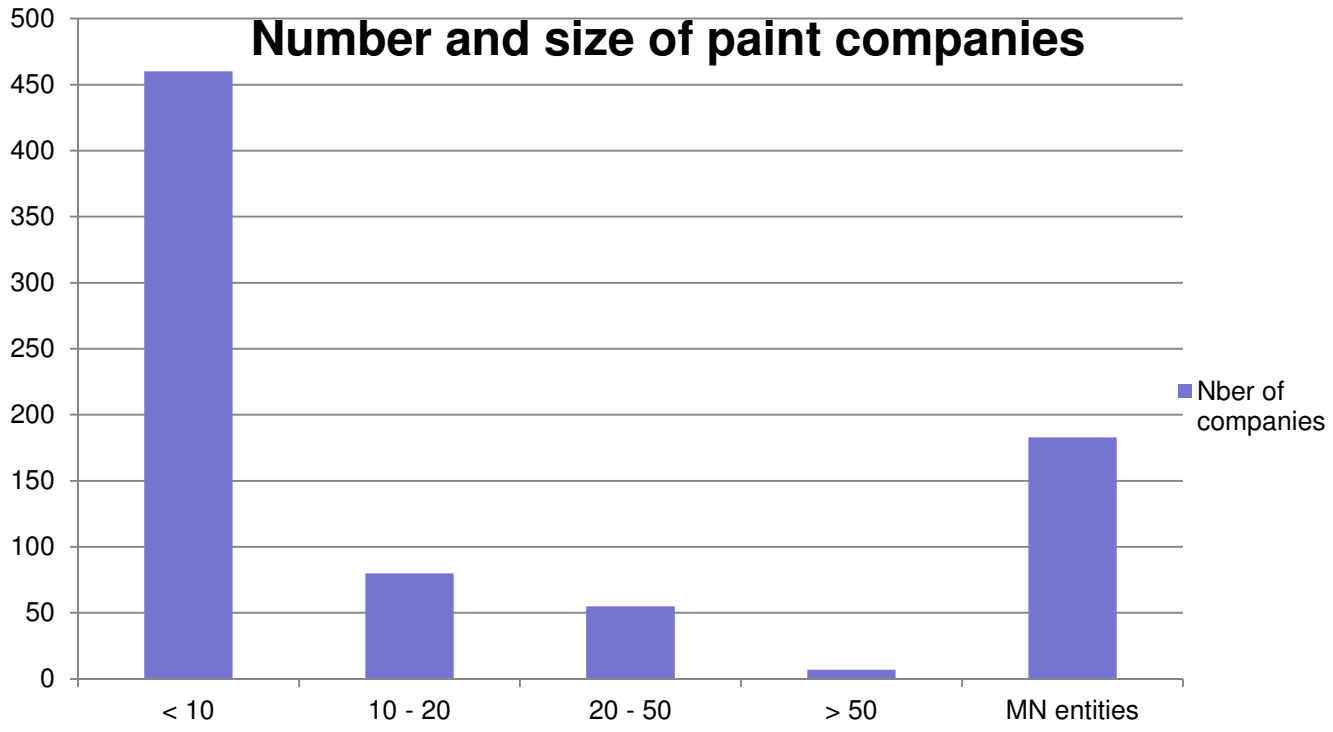
CEPE the EU collective body that represents:	
Companies	Value
App. 800 paint producers	13 billion EUR/y
75 printing ink	3 billion EUR/y
20 artists' colours	0.3 billion EUR/y
110,000 people directly employed	85% of market value

Structure of paint producers in W-EU



Turnover in millions €

Inside CEPE

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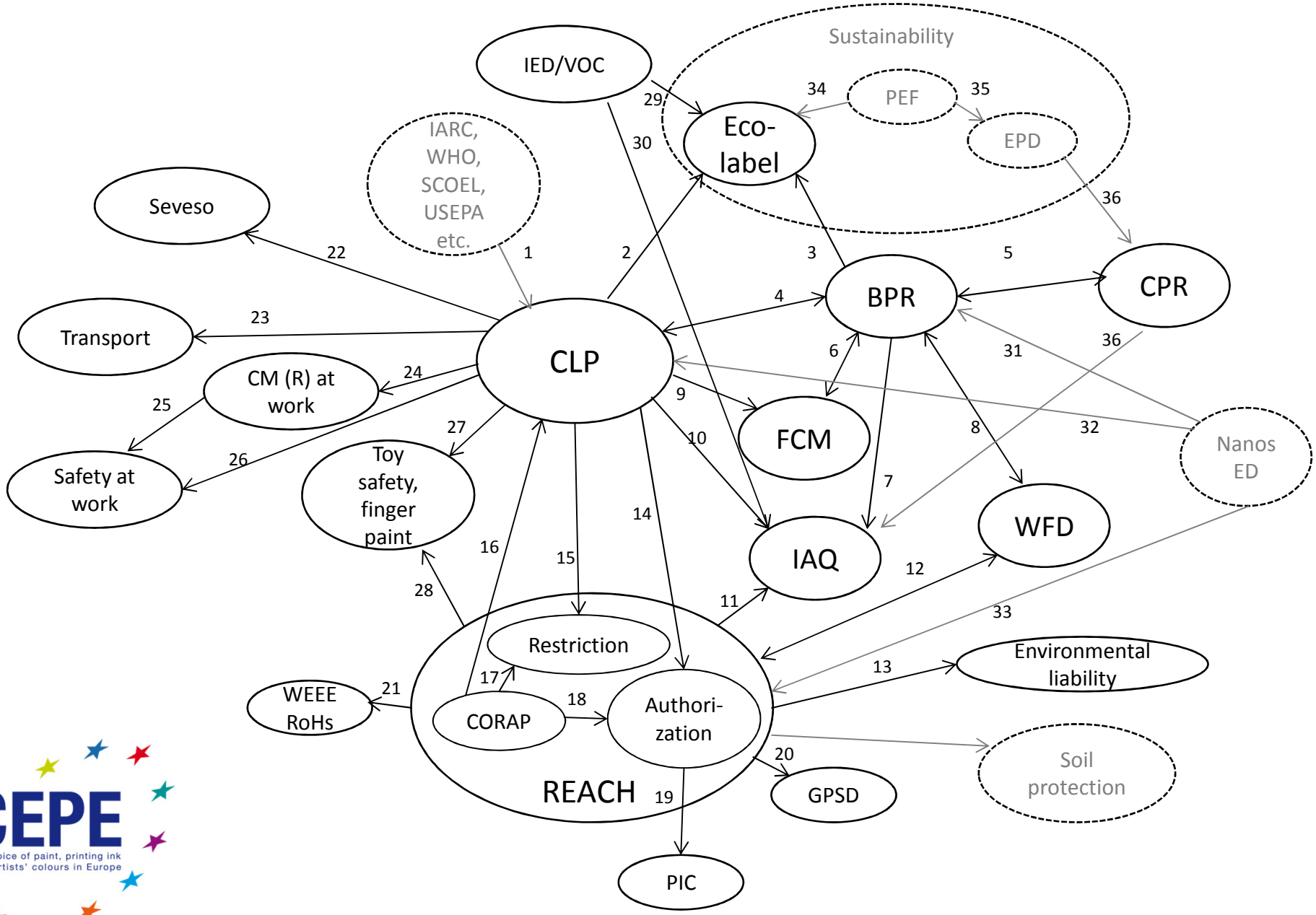
- About 250 company representatives (companies and National Associations) involved in ~ 40 CEPE meeting bodies to address issues on:
  - intra-industry guidelines and standards
  - industry image
  - advocacy

- CEPE sectors (vertical):
  - Aerospace Coatings
  - Can coatings
  - Decorative Coatings
  - Marine coatings
  - Protective Coatings
  - Inks (EuPia)
  - Artists' colors
  - Coil Coatings
  - Industrial Wood coatings
  - Powder coatings
  - Vehicle Refinishes Coatings

Inside CEPE

- CEPE horizontal groups:
  - REACH Panel
  - Exposure Scenarios
  - LSDS
  - Transport
  - OSRA (Occupational Health)
  - ToxAg
  - SHEAB
  - Food contact (in EuPia and Can coating)
  - Sustainability
  - Indoor air
  - Nanos
  - Ecolabel
  - VOC/CAFE
  - And Biocides

Activities and legislations impacting the coating & printing ink industry and their inter-connections



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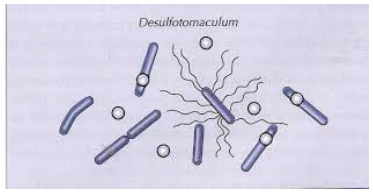
CEPE and Biocides

CEPE and Biocides

- Limited involvement in product authorization: anti-Fouling paints, wood preservatives
- Most CEPE members are downstream users of PT6 and PT7 products and produce water based products so need in-can preservatives
- Decorative paint: 85% now WB due to VOC reduction, so <u>in-can preservation is essential</u>

-> CEPE is DU of PT6 biocidal products

Why in-can preservatives?

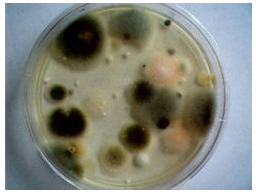


Water + organic matter = food for micro-organisms

- Multiple bacteria: *Pseudomonas aeruginosa*, *bacillus subtilis, Esterichia coli, Acetobacter aceti, Staphylocossus aureus, Desulphotomaculum, Micrococus* etc.
- Multiple fungi: *Alternaria alternata, Aspergilius niger, Cladosporium sp, Penicilium sp., Geotrichum etc.*
- Multiple yeasts: *Sacchamomyces cerevisae, Candida albicans, Rhodotorula etc*

-> Multiple organisms, **need wide spectrum control**

Damages caused



Damages caused

- Destruction of ingredients, product function lost
- Discoloration
- pH change
- Change of viscosity
- Gas and smell generation
- Development of biofilms (manufacturing plants)
- Threat to health for workers/users

-> Wet paint rots within days without preservation.

Available tools?

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Available tools for in-can preservation

- 47 existing PT6 substances supported: 13 formaldehyde releasers, 5 isothiazolinones (incl. 1 fungicide) Biocide Users of PT6 Impact assessment final Oct 14.pdf
- Several of no interest: in the list for other reasons
- Others? Most are not useable at all in our products for different reasons:
  - not technically compatible (surface actives, acids, smell, color..)
  - limited efficacy (short life, intrinsically limited efficacy)
  - uncertain safety profile
- 3 'new actives': folpet (old substance tested many years ago, not used as hydrolyses very quickly at typical pHs); MBIT (another isothiazolinone); silver nitrate (limited efficacy)

-> **we need the existing tools**, esp. CH2O releasers and isothiazolinones

CH2O releasers

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Formaldehyde releasers

- Used for decades
- Proven efficacy
- Various kenetic of degradation alowing 'fast action' and 'long term protection'
- Headspace control (air present in the can bewteen the paint and the top)
- Some weaknesses, often used in association with other actives
- But outstanding cost/efficacy ratio
- No issue of safety in use, CEPE Members happy to use them

CEPE Concerns for PT6

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Threat No 1 for in-can: classification for the releasers as Carc. 1b

- AU proposed 3 CLH dossiers to RAC + public consultation for MBM as candidate for substitution with justification:
  '*the releaser breaks down in contact with biological tissues and hydrolyses to formaldehyde, consequently the toxicity of the parent compound is related to the toxicity of formaldehyde*'
- If that logic stands all releasers impacted?
- Also, confirmation was made that all releasers dossiers rely on CH2O for the chronic endpoint -> duality 'classify as it stands' >< 'classify based on the endpoints of the dossier'.

Can we do without?

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Can we do without formaldehyde releasers?

Cost considerations put aside, if all other in-can remain it should be possible to do without

HOWEVER:
- is it wise to reduce modes of action for resistance management?
- what is the future of the other PT6 actives?

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Threat No 2 on in-can: not enough different modes of action

- TOLERANCE (resistance)
- Bacteria multiply x 2 every 20 min. in good conditions
- High mutagenic change = high chance of new resistant gene
- Resistant bacteria = huge problems
- 2 key elements to avoid this:
  - maintain sufficient diversity of tools (modes of action)
  - Maintain efficient enough tools
- Formaldehyde releasers and isothiazolinones are proven well effective tools used for decades. Multi-site of action, how would resistance develop without them? Unknow yet.

-> **Do we want to take the risk?**

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Threat No 3 on in-can: skin sensitizing profile of isothiazolinones

- Isothiazolinones = second main family
- 3 main bactericides: BIT, MIT and CMIT/MIT (OIT is fungicide)
- Used under classification limit but EUH 208 for elicitation sentence will be applied in many cases from June 2015
- All skin sensitizers of different potency
- Threat is to have severe restriction of use
- Some MS already want to severely restrict MIT (started at BPC 7)

-> **We believe that other solutions than severe restrictions should be tried**

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Threat No 4: future of the other in-can

- Detailed supported uses unknown
- Outcome of the review for safety of use unknown
- Worse classification likely

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Uncertain future, need holistic approach

- Current system does not require impact assessment
- Individual decisions on a.s., no holistic approach
- If key in-can biocides are restricted/banned and then we reach a shortfall of solutions, what is next?
- Need to derogate, approvals limited in time, constant renewal mode

- Fine if there is safety issue (we need a biocide legislation)
- But if there is no risk, is it really necessary?

Real risk?

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Do formaldehyde releasers pose a real risk?

- Formaldehyde has threshold
- Used at low concentrations, typically 0.01-0.02%
- Can the frequency of exposure lead to chronic irritation of naso-pharyngal tract leading to cancer effects?
- MBM just approved for PT6 for diesel fuel show acceptable risk
- The BPR has (also) a risk based approach and will tell

Conclusions

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- High regulatory pressure has consequences that should be understood beforehand
- Riding in the dark , need lights to see colours?

- If safe uses are confirmed for formaldehyde releasers, do we really need to regulate under BPR Art 5 and 10?
- Can the benefits of biocides be recognized to their value?
- Hazard >< risk: will risk based approach be necessary to stop the hemorrhage

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THANK YOU FOR LISTENING !

Conclusions

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I hope that I helped understand a little the consequence of the heavy regulatory pressure on biocides and helped question whether this is not going too far.
Releasers may not be necessary if isothiazolinones remain with other complementary in-can actives, but these also have an uncertain future and we have to be careful NOT to promote bacterial resistance by reducing too much the available tools.

What is the solution? Under the current process there is no easy solution: MS are submitting PT6 dossiers at different times and RAC has to process the CLH dossiers.

The real question is whether there is a real risk of using them. Because if there is no risk in use, we should question whether all this is necessary. The same reflection is happening now under REACH: is the Authorization route the best regulatory route for general chemicals? Are we not going too far in Europe? This debate has started at high level in Europe, and it is time that we apply this to the biocide legislation as well: we need simplification and a real risk based approach.