





PRESERVATION OF PAINTS & DETERGENTS

WORKSHOP ON INNOVATION AND INDUSTRY CHALLENGES

Wednesday 15 May 2019, Brussels, Belgium

PROCEEDINGS

Summary

Last year the European Commission invited Member States, industry and NGOs to initiate actions towards finding alternatives to active substances in areas where innovation is needed. Preservation for products during storage was identified as one of the priority areas.

Building on these recommendations, A.I.S.E. and CEPE organised a workshop on biocide preservation in the paint and detergent sectors, to discuss with all interested parties the current innovation in the fields, challenges faced by industry, and possible solutions under the Biocidal Products Regulation (BPR).

The morning session started by looking at attempts to innovate both from biocides' suppliers and downstream users' perspective. Speakers discussed existing solutions as well as current technical and regulatory challenges. This was followed in the afternoon by a number of breakout sessions where all participants had the opportunity to reflect further on short to long term solutions, either from a regulatory or product innovation point of view, to ensure that product preservation remains available in the future.

Participants acknowledged that the use of preservatives in paints, printing inks and detergents is indispensable in the short/medium term, and that future availability of suitable preservatives is uncertain; it was therefore concluded that the issue has to be addressed in a pragmatic way under the BPR.



Agenda of the workshop

8:30 - 9:00 Registration & welcome coffee

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PART 1: CONF	ERENCE (PLENARY SESSION) - Moderator: Hugues Kenigswald, Head of Unit, ECHA
9:00 - 9:15	 Welcome & Introduction Susanne Zänker, Director General, A.I.S.E and Jan Van der Meulen, Managing Director, CEPE
9:15 - 9:35	The BPR legal framework and the review programme • Ludovic Chatelin, Policy Officer, European Commission, DG SANTE
9:35 - 10:05	Addressing the future availability of in-can preservatives Didier Leroy, Technical Director, CEPE Hanne Jensen, R&D Manager Biology, Jotun
10:05 - 10:25	Innovation for biocides: a supplier's perspective Rodolphe Quérou, Global Regulatory Affairs Manager, DuPont
10:25 - 10:45	Q&A session
10:45 - 11:15	Coffee break
11:15 - 11:45	Innovation for biocides: downstream users' perspectives Jan Lorenzen, Senior Project Manager, Danish Technological Institute Elodie Cazelle, Senior Scientific & Regulatory Manager, A.I.S.E.
11:45 - 12:15	 CLP: hazard warning for skin sensitising substances and consequences under the BPR Johanna Bernsel, Deputy Head of Unit, European Commission, DG GROW Gerard Luijkx, Regulatory Affairs Manager Home Care, Unilever
12:15 - 12:30	Q&A session
12:30 - 13:45	Lunch break
	KOUT PARALLEL SESSIONS Y PLENARY - Moderators: Mary lakovidou, KEMI, Sweden, and Didier Leroy, CEPE
13:45 - 15:30	Can we do without in-can preservatives (PT6)? (Moderator: JaapTuinstra, Ministry of Infrastructure and Water Management, Netherlands)
	2. Can we do without dry-film preservatives (PT7)? (Moderator: Ute Schoknecht, BAM, Germany)
	3. How to inform consumers to ensure their protection from skin sensitisation (Moderator: Douglas Hunter, Ministry of Environment and Food, Denmark)
	4. What solutions within the BPR legal framework could be found in the short-term to secure continued safe and effective products? (Moderators: Mary Iakovidou, KEMI, Sweden, and Steven Fauconnier, FPS Public Health, Food Chain Safety and Environment, Belgium)
15:30 - 15:50	Coffee break
15:50 - 16:45	Feedback from the breakout sessions in plenary
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Appointed group representatives

Closing remarks and next steps

Closing drink

16:45 - 17:00

17:00 - 18:00

Proceedings

PART 1: CONFERENCE (PLENARY SESSION) - Moderator: Hugues Kenigswald, Head of Unit, ECHA

Susanne Zänker and Jan Van der Meulen, the Managing Directors of A.I.S.E. and CEPE welcomed the participants and opened the workshop explaining how important biocide preservatives are for their respective sectors.

Ludovic Chatelin from DG SANTE started to explain the status of the BPR review with particular focus on preservatives, as well as previous agreement concluded in guidance documents for treated articles. Programs to promote substitution and previous workshop on other biocide Product Types (PT) were mentioned. Industry was called to make every effort to answer societal and regulatory expectations through innovation.

Didier Leroy from CEPE underlined that Industry has taken note for many years on the need to decrease the use of biocide preservatives as much as feasible to answer to societal concerns. However, time has come to be realistic about solutions that are needed under the current BPR framework to avoid a crisis. He introduced the topics of the day by touching on the needs and the benefits of preservation, the limited number of actives that can actually be used, and the importance to address what can be done to innovate.

Hanne Jensen from Jotun, a paint company, then explained in more details that preservation is a complex topic due to the nature of the organisms that require control and the technical difficulties to find suitable preservatives. Microorganisms are everywhere, biocides are essential, there is no 'one-fits-all solution' and biocide actives must be combined to offer the necessary protection and avoid building tolerance. To be more precise, the key actives were specifically named and their problems listed. Biocide preservatives are essential to reduce the use of natural resources and reduce the emissions, they are part of the solution for a sustainable future.

Because of the general call for innovation, Rodolphe Quérou from DuPont, a biocide supplier, explained how this topic is considered from their angle. Innovation is not only to bring new active substance on the market. It is also part of a variety of integrated solutions such as microbial control strategies, dosing systems, packaging, plant hygiene or formulations. In order to introduce new biocide substances, the simplest option is to look at variations of existing chemical families or sourcing from adjacent markets (like e.g. Plant Protection). In order to use existing substances differently options like controlled release formulations are possible. But all of this has a significant cost and requires substantial business justification before management approves. Incentives for innovation are needed given the extreme financial, technical and regulatory challenges. Biocide suppliers need an innovation-friendly regulatory environment and time (as product development usually takes between 5-10 years).



Jan Lorenzen from the Danish Technological Institute presented the outcome of a research programme financed by their government and in partnership with a local paint company. The objective was to identify possible routes to reduce or eliminate the need for in-can preservation. Several options were investigated: plant hygiene, new paint formulations based on cleaner raw materials or raw materials less susceptible to microbial attack, the improvement of biocidal effect using some co-formulants, a significant increase of the pH and other ways such as pasteurisation or developing powder paints. It was concluded that Industry cannot do without a at least residual biocidal effect in cans.

Elodie Cazelle from A.I.S.E. then explained the breadth of products that need in-can preservation in the detergent and cleaning products industry and the extended efforts that the industry already made, looking after solutions like the optimisation of product composition, high or low pH or solid formulations. As an example, it is possible to manufacture concentrated detergents that do not require in-can preservation, but which then cause other inherent problems such as more hazardous products. Powder forms require more energy to produce and there is a clear market demand for water-based products. The Green Chemistry and Commerce Council GC3 project was also mentioned which could not identify short-term to mid-term alternative solutions.

As an introduction to the skin sensitization problem, Johanna Bernsel from DG GROW informed that in Europe also another Regulation applies to biocidal products, namely CLP, which is directly related to the Global Harmonized System of the UN. This Regulation entered into force 10 years ago and superseded a classification system in existence in Europe since 1967. CLP provides hazard information both for substances and mixtures. It sets threshold concentrations above which labelling obligations start. It is a purely hazard based system that does not consider exposure, hence does not consider whether there is a risk or not. The regulation addresses all kinds of hazards for the human health and for the environment. This also covers skin sensitization.

The final presentation of the morning was provided by Gerard Luijkx from Unilever, a detergent manufacturer. The EUH 317 classifies the chemical mixture as skin sensitizer above a threshold to cover the hazard of skin sensitization induction (first exposure) as well as it requires a specific warning sentence from 1/10th of that level to cover skin sensitization induction (for those previously exposed who developed skin allergy). Labelling examples were provided to illustrate that consumers already have access to many information linked to CLP but also required by the specific Detergent Regulation and the BPR. Communication could be improved by avoiding duplication of information. The difference between hazard and risk was made. This is relevant since under the BPR safe use might be identified, but it remains possible to see an active substance excluded based on hazard.



PART 2: BREAKOUT PARALLEL SESSIONS

FOLLOWED BY PLENARY - Moderators: Mary lakovidou, KEMI, Sweden, and Didier Leroy, CEPE

Participants were divided into 5 groups who discussed in parallel 4 different themes related to innovation in the field of PT6 and PT7, how to inform consumers to ensure their protection from skin sensitisation, and possible solutions in the short term under the BPR framework. Then the moderators of each group reported to the plenary, followed by a short discussion and conclusions.

Breakout session 1: Can we do without in-can preservatives (PT6)?

Moderator: JaapTuinstra, Ministry of Infrastructure and Water Management, Netherlands

The group exchanged views on several themes including why preservatives are needed in paints, inks and detergents, alternative options (such as sterilisation), use of biocides (availability, range of action, combination of actives) and why a broad range of actives is needed (e.g. to prevent resistance). Some examples of preservative-free formulations were discussed, and the participants recognised that whilst some solutions exist for very specific products (e.g. high pH matt white indoor wall paints, laundry powder detergents), those are always associated with some drawbacks and there is no 'one-size-fits-all' solution.

As a conclusion, all participants of breakout session 1 agreed that in the short term (i.e. about five years), in-can preservatives are indispensable.

Breakout session 2: Can we do without dry-film preservatives (PT7)?

Moderator: Ute Schoknecht, BAM, Germany

The CEPE document from May 2016¹ that lists active substances and comments on their applicability was distributed to the participants as a starting point for the discussion. The following aspect was added to the presentations from the morning session: the energy saving due to insulation of buildings causes higher risk of microbial growth on surfaces (lower temperatures, increased humidity). This also leads to the need of film preservation.

During the discussion it was illustrated why there is only a limited number of currently reviewed active substances from the PT7-list that can be actually used in coatings.

The classification of active substances is not that much of a problem, but the BPR hazard-based approach which triggers in some instances the exclusion criteria under Art 5, which hinders product innovation due to market access uncertainties. It was agreed that the hazards presented by these actives exist and risks should be prevented through risk mitigation measures.

In Nordic countries DIY use of paints is very common. Producers of paints expect that it is possible to demonstrate safe use of paints that include active substances above the classification Specific Concentration Limit (SCL).

On risk assessment for these preservatives, it was highly recommended to use dialog between applicants and authorities to discuss relevant protection goals, market share of the actives and realistic exposure scenarios and to make sure that current knowledge can be considered.

Overall the benefit of PT7 products was recognized. It was also accepted that innovation in biocide-free alternatives is limited. It was accepted that there can be a shortage of active substances for film preservation. The intrinsic hazard of the actives should be mitigated through risk management measures and a dialogue between Industry and Competent Authorities is encouraged to find solutions.

¹ The need for a holistic approach on dry-film preservatives - The benefits of dry-film preservatives and the consequences of losing effective protection on the sustainable use of paint, CEPE, May 2016

Breakout session 3: How to inform consumers to ensure their protection from skin sensitisation

Moderator: Douglas Hunter, Ministry of Environment and Food, Denmark

The group discussed the following questions: Do products containing skin sensitizers present an unacceptable risk? How do we protect end users? Are additional measures available? Is CLP enough to inform the general public of a skin sensitizing hazard? Is there a need for additional precautionary measures under the BPR?

There was agreement that CLP should not be questioned, since it is a horizontal legislation providing information on hazard, it should therefore be sufficient to inform consumers. BPR Article 58 (placing on the market of treated articles) comes 'on top of' CLP and goes further on basis of risk assessment. A way forward could be to demonstrate that the risk of sensitisation is managed at product authorisation level, in order to avoid introducing restrictive conditions in the active substance approval decision.

The specific case of CMIT/MIT was also discussed, it was agreed that the threshold limit for use in treated articles of 15 ppm (Specific Concentration Limit) is appropriate since CMIT/MIT is still efficient at such low concentration. However other isothiazolinones have different potency, so it may be appropriate to use another value than the SCL when assessing risk (e.g. EC3 value).

The group concluded that a solution is needed to continue using existing preservatives, and that the CMIT/MIT restriction should not be followed for other isothiazolinones, as this would lead to a *de facto* ban of these actives.

Breakout session 4: What solutions within the BPR legal framework could be found in the short-term to secure continued safe and effective products?

Moderators Mary Iakovidou, KEMI, Sweden and Steven Fauconnier, FPS Public Health, Food Chain Safety and Environment, Belgium

Two different groups discussed in parallel this theme.

All agreed as a starting point that there is an issue related to the future availability of preservatives, and that one of the major concerns is that the approach taken for CMIT/MIT creates a precedent for other isothiazolinones.

The following options were discussed:

- Possibility for a holistic approach, i.e. harmonise dates of review and approval of PT6 active substances, but it was recognised that as a standalone measure this would not necessarily solve the above-mentioned issue.
- Consideration of socio-economic impact information: although this is required only in the case of active substances subject to exclusion criteria, such information could be submitted to the evaluating Competent Authority for further consideration in the active substance dossier.
- With regard to the CMIT/MIT case, it was recognised that there is no legal basis for imposing restrictions in treated articles for use by the general public in case the active is a skin sensitizer. The only reference is a guidance note from 2013 (CA-Sept13-Doc.6.2.a), it was suggested to revise this note. It was also suggested to keep the active substance approval decision as 'open' as possible, demonstrating safe use at biocidal product authorisation level.

The recommended next step from this break out session was for the Commission to work further on the issue, in the form of a Competent Authorities document to clarify and discuss issues before active substances review, in a similar way as for antifouling active substances (PT21) (CA-March14-Doc.4.2).

Industry was also invited to contribute actively to public consultations (in case of exclusion criteria).

Conclusions

All participants agreed that there is an issue related to the future availability of preservatives (PT6 and PT7) and that the use of preservatives in paints, printing inks, artists' colours and detergents is indispensable in the short/medium term. The workshop was concluded with a recommendation to take the topic to the Biocides Competent Authorities level as next step: ideally the Commission shall take the issue forward, developing a paper similar to the Competent Authorities note on antifouling (CA-March14-Doc.4.2 "Antifouling (PT21): Way forward for the management of active substances and the authorisation of biocidal products") agreed in 2014.

All participants were thanked for their active contribution.

Annex: participants list (as registered)

First name	Last name	Company/organisation name	Country
Maria	Amon	Federal Ministry for Sustainability and Tourism	Austria
Maarten	Asberg	PPG	Netherlands
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Johanna	Bernsel	European Commission	Belgium
Carsten	Bloch	Federal Institute for Occupational Safety & Health	Germany
Cristina	Bocca	Boero Bartolomeo SPA	Italy
Henri	Botter	AkzoNobel	Netherlands
Tom	Bowtell	British Coatings Federation	UK
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Anastasia	Burmistrova	FPS Environnement - Belgium	Belgium
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Germaine	Truisi	Thor GmbH	Germany
Gitte	Tuesen	Danish Coatings and Adhesives Association	Denmark
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lan	Watt	Dow DuPont	UK
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About A.I.S.E. and CEPE

A.I.S.E., the International Association for Soaps, Detergents and Maintenance Products, is the official representative body of this industry in Europe. Our membership totals 29 national associations across Europe, and over 900 companies supplying both household and professional cleaning and maintenance products and services across Europe. A.I.S.E. represents a turnover of 36 billion € and 95.000 jobs directly and 360.000 in the value-chain.

CEPE (Paints, printing inks and artists' colours in Europe) represents approximately 85% of the industry with a value of around 17 billion €. In total 120.000 people are directly employed and the people that apply the products are a multiple of this number.

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