



Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien  
International Association for Soaps, Detergents and Maintenance Products

# BPR Opportunities and challenges for biocidal product formulators in 2014

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**Biocides Stakeholders' Day**

24 September 2014

*Working together for a cleaner Europe*



# Introducing A.I.S.E.

## International Association for Soaps, Detergents and Maintenance Products

A·I·S·E

- **Members:**
  - 37 National Associations in 42 countries
  - 9 direct member companies
- **About 900 companies - 60% SMEs**
- **Consumer and Industrial & Institutional (I&I) markets**
- **Biocidal Product Formulators**

- **Disinfectants:**

|   |
|---|
| PT1 Human Hygiene                               |
| PT2 Disinfectants and algacides (surfaces, etc) |
| PT3 Veterinary hygiene                          |
| PT4 Food and feed                               |
| PT5 Drinking water                              |

- **In-can preservatives: PT6**

- **Insecticides and repellents: PT18 and PT19**



# Importance of biocides for A.I.S.E.

- Market assessment 2011 \*

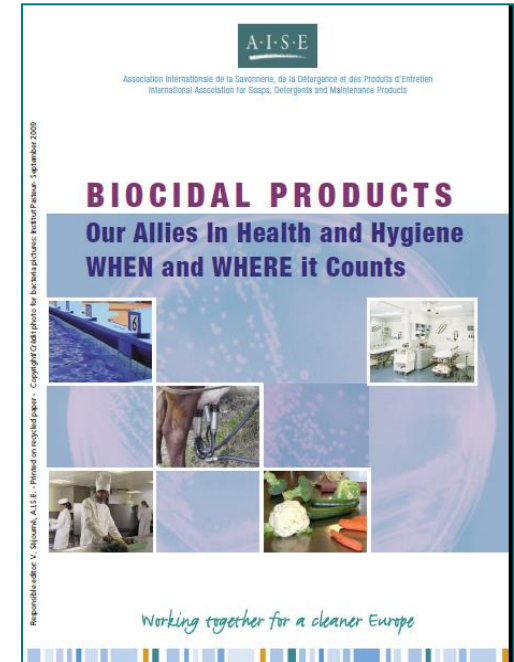
| Nb of products (2011) | Actives approved (2014) |
|-----------------------|-------------------------|
| PT1 ~ 200 products    | 2 actives / 37          |
| PT2 ~ 3300 products   | 3 actives / 88          |
| PT3 ~ 400 products    | 3 actives / 55          |
| PT4 ~ 550 products    | 6 actives / 56          |

- Many SMEs

- Products delivering benefits everyday

- ✓ Consumers safety: prevent food contamination, water purification
- ✓ Limit contamination: disinfection in hospitals (e.g. linen), hands, homes
- ✓ Animal welfare: disinfection of stables
- ✓ Insect control: prevent infestations, insect-borne diseases

\* A.I.S.E./EBPF Survey 2011 with input from 90 companies (across all PTs)



# What did we say in 2012 when BPR was adopted?

## We welcomed

- Union Authorisation: **harmonisation**
- Concept of Biocidal Product Families: **reduced costs and administration**
- Time-limited and streamlined procedures: **predictability**
- Some barriers to MR lifted: predictability
- Changes Regulation and Same Products Authorisation: less administration, less restriction on commercial practices
- ECHA's involvement : science, IT, support, data sharing
- Simplified authorisations ? Principle is fine, conditions too restrictive

# What did we say in 2012 when BPR was adopted?

## We regretted

- Prohibitive Fees, in particular for SMEs
  - Exclusion and substitution based on hazard, regardless of risk
  - Complexity of Treated Articles requirements
  - ECHA not having an evaluation role for biocidal products
- 
- More generally, benefits of biocidal products not fully recognised

# Where do we stand in 2014?

## Union Authorisation

- The whole process has not been fully tested yet: **need to build trust**
  - First applications are being made (PT3-PT4)
- ECHA's support is appreciated
- Pre-submission meeting is both needed and useful (eCA + ECHA)
- UA eligibility restriction (timelines, actives) is not an issue at this stage
- **Costs create barriers:** we are particularly concerned with 'double annual fees'

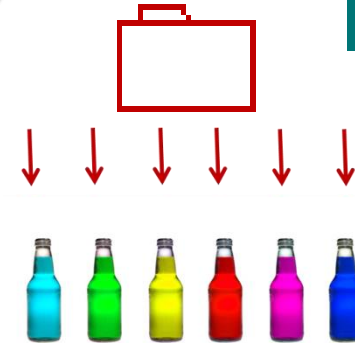



Case study (SME): authorisation for 5 products in 18 countries

UA (10 yrs)= 2.3 M€, up to 3.7 M€ if MS apply annual fees on top of ECHA fees

# Where do we stand in 2014?

## Biocidal Product Families



- Correction to unnecessary restriction ‘same classification’ for individual products within a family (2014) 
- Concept still under development: companies need **clear guidance soon**
- **Three-level approach is pragmatic and realistic, it also sets limits**

### Level 1: Overall Information on BPF

admin, type, broad composition, list of PTs

### Level 2: Meta-SPC, sub-grouping by use

one meta-SPC = one RMM set, same C&L, same instructions

### Level 3: Individual products

exact composition

# Where do we stand in 2014?

## Other improvements we welcomed in 2012

Biocides Stakeholders' Day  
24 September 2014, Helsinki, Finland

- ✓ **Procedures: clearer and more predictable timing**
  - ➔ Shorter! start biocidal product dossier from BPC Opinion
- ✓ **ECHA: procedures and IT-tools in place, some new guidance developed**
  - ➔ More support to SMEs, simple tools (e.g. cost comparison, tracking dates)
  - ➔ Access to committees limited to ASO, too few experts allowed
- ✓ **Simplified authorisation: does not seem to create an incentive**
  - ➔ For some applications, the actives are not effective enough
  - ➔ The limitation to non-classified biocidal products is an unnecessary hurdle
- ✓ **Building consortia for biocidal product (family) authorisation?**



# Challenges formulators are currently facing

## New concepts, new requirements, new uncertainties

- **In-situ active substances**
  - **Pragmatic approach** proposed based on 'main precursor + in-situ active'.
  - Implications for formulators: **Article 95 listing, technical equivalence ?**
    - ➔ **Industry needs the rules to be set URGENTLY**
- **Application of Article 95: 1 September 2015 deadline**
  - ➔ How to reach all BP formulators concerned?
- Substitution criteria, comparative assessment ...
- Derogation to exclusion criteria ...
- Uncertainty on classification CLH vs exclusion /substitution criteria

# Challenges formulators are currently facing

## More uncertainties on the horizon

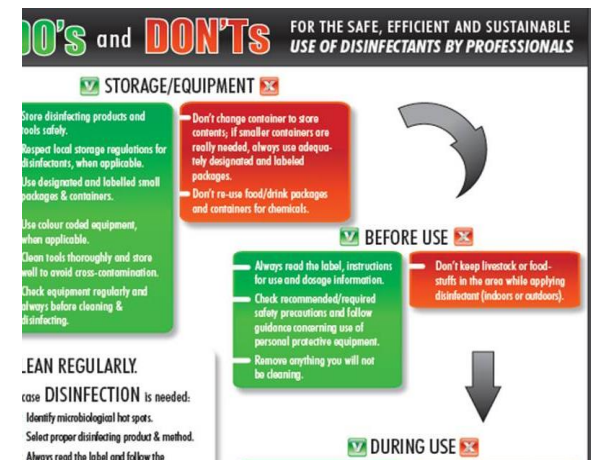
- The case of in-can preservatives

- ✓ Formaldehyde releasers: classification issue
- ✓ Isothiazolinones: sensitisation issue
- ✓ Others? No clear alternative

How do we secure effective and sustainable preservation?

- Sustainable use of biocides?

- Fees: national and Union ?



# Challenges formulators are currently facing

## Treated Articles

- Correction to the transition period (2014)
- Implementation is more complex than expected
  - '[...] treated with, or **intentionally** incorporates [...] biocidal products': based on claims, concentration of substance, PT.  
But no threshold !
  - **Complex articles:** 'finished goods' pragmatic solution
  - 'Public health' claim concept ?
- **Primary biocidal function** : the differentiator between biocidal products and treated articles
- Labelling of articles at active approval stage, e.g. IPBC
- Labelling for skin sensitisers goes beyond CLP for mixtures !



Preserved liquid detergents



- We are hopeful that Biocidal Product Families and possibly Union Authorisation represent an improvement over BPD
- **We need stability and predictability:** there are still too many ‘moving targets’ (in-situ, treated articles)
- **Marketing biocidal products is a long, cumbersome, complex and expensive task:** the market will change...
  - Disappearance of actives and products
  - Switch from SMEs to multinationals
  - Limited innovation
- **We need enough actives and products approved to secure hygiene standards:** this is about public health!
- SMEs need to be supported: requirements are extremely complex
- A.I.S.E./EBPF will run a **BPR Impact Assessment Survey** soon

**Read the label!**  
What you need to know to ensure safe use of  
detergents and cleaning products in the home



- ➔ New warning labels will soon be appearing on household cleaning products.
- ➔ Some of the updated and safety information you may be used to seeing will change.
- ➔ Our label will show the product itself or different parts not all products are affected.
- ➔ This label explains the changes to help you make sure you keep using these products safely.

**REMEMBER:  
PLEASE READ THE LABEL.  
FOLLOW THE INSTRUCTIONS PROVIDED.**

**Read the label!**  
Information for industrial and institutional  
users of detergents and cleaning products



- ➔ Due to the implementation of the updated regulations on classification and labeling of chemicals, new warning labels will soon be appearing on all products.
- ➔ All danger symbols, risk and safety information that you used to see, may change but this does not mean that the products are different.
- ➔ This label explains the changes to help ensure safe use and handling of detergents and cleaning products.

**REMEMBER:  
PLEASE READ THE LABEL.  
FOLLOW THE INSTRUCTIONS PROVIDED.**

# THANK YOU FOR YOUR ATTENTION