

The BPR legal framework and the review programme on preservatives

**AISE-CEPE Workshop on preservatives in paints and detergents
Workshop on innovation and industry challenges
Brussels, Belgium
15th May 2019**

- I – Implementation of BPR**

- II – Status of in-can preservatives PT06 and film preservatives PT07**

- III – The BPR and treated articles: the 2015's agreement on labelling provisions**

I – Implementation of BPR

Application of the BPR

- **Regulation (EU) No 528/2012 (BPR) proposed 10 years ago, adopted 7 years ago, and entered into application on 1st September 2013**

- **22 different product-types, including :**
 - ❖ PT06: in-can preservatives (ex: in detergents, paints)
 - ❖ PT07: film preservatives, to protect during service-life (ex: in paints, coatings, sealants etc.)

- **Replaced the previous Directive 98/8/EC, evolutions:**
 - **New procedures:** AS approval procedures, National authorisation / mutual recognition procedures, Union authorisation, Applications to ECHA for registration on the AS suppliers list (art. 95), etc.

 - **New provisions and principles:** Exclusion (C/M/R, PBT/vPvB, ED) / substitution of active substances, comparative assessment of biocidal products, treatment and Labelling provisions of treated articles (art.58), etc.

Provisions in BPR to reach safety objectives and give incentives to develop alternatives to problematic AS

- **In various ways, incentives/promotions via :**
 - Approval & Authorisations provisions
 - Exclusion provisions
 - Substitution provisions
 - Comparative assessment of BPs
 - Annex I, simplified authorisation procedures
 - Provisions on treated articles
 - Provisions on sustainable use

Approval of AS : Exclusion criteria (art. 5)

Objective : *exclude substances of very high concern*

- **Substances that :**
 - are Carcinogens, Mutagens, or toxic for Reproduction category 1A or 1B, or
 - are Persistent, Bioaccumulative and Toxic, or very Persistent and very Bioaccumulative, or
 - have endocrine-disrupting properties

- **The principle: the active substance cannot be approved**

Approval of AS : Exclusion criteria (art. 5)

- **The derogation: Substances may nevertheless be approved if:**
 - Exposure is negligible, or
 - The substance is essential to control a serious danger to human or animal health or to the environment, or
 - Non-approval will have disproportionate negative impact for society
- If so :
 - Strict provisions for their approval, and authorisation only in MS where needed
 - Approved for a maximum of 5 years
 - Targeted by the substitution provisions
- **Biocidal Products to be authorised only in MS where the derogation conditions are met**

Approval of AS : Substitution (art.10)

Objective : Substitution of substances of less concern than the one targeted by exclusion, but still of high concern

A substance is listed for substitution if it fulfils one the following criteria :

- Fulfils the exclusion criteria (but has nevertheless to be approved)
- Is a respiratory sensitiser,
- Has significantly lower Acceptable Daily Intake, Acceptable Reference Dose or Acceptable Operator Exposure Level than similar substances,
- Meets two P/B/T criteria,
- Gives concern linked to critical effects (e.g. high potential risk to groundwater), or
- Contains a significant proportion of non-active isomers or impurities.

→ Approved for a maximum of 7 years (5 years for exclusion AS)

Approval of AS :

Comparative assessment of BP (art.23)

Objective : forbid or restrict the making available on the market of BP with AS candidate for substitution, to promote substitution and innovation

- **Consequence of substitution of AS : comparative assessment of BP**
- **Made during the assessment of the authorisation of the BP or the renewal of authorisation, either at MS or EU level**
- **Products containing candidates for substitution will be restricted or not authorised if:**
 - Alternatives available
 - Present significantly lower risk
 - Are sufficiently effective, and
 - Present no significant economic or practical disadvantage, and
 - Chemical diversity adequate to minimise resistance
- **Possible derogation for Member States to perform a comparative assessment for a maximum of 4 years in order to gain experience**

→ **Authorisation of BP for a maximum of 5 years**

Treated articles (Chap. XIII, art. 58)

Objective: Ensure protection of health and the environment in EU, ensure better competition between treated articles that are treated in EU and those treated outside EU, better information of customers/consumers to make informed choices

□ **Definition of "treated articles" (e.g. preserved detergents, paints):**

- Substance, mixture or article (according to REACH definitions)
- Treated with or intentionally incorporating biocidal products

□ **Allowed on the market only** if all the active substances contained in the BP are approved for the relevant product type or included in Annex I to the BPR, and it complies with relevant conditions of approval of the AS

□ **Guidance on Treated articles "CA-Sept13-Doc 5.1.e (Rev1) - treated articles guidance.doc", borderline BPs/TA:**

<https://circabc.europa.eu/w/browse/d7363efd-d8fb-43e6-8036-5bcc5e87bf22>

Labelling of certain treated articles

- **Required if**
 - Case 1: Claim is made regarding biocidal properties of the mixture/article (e.g. film protected against development of fungi etc.)
 - , or
 - Case 2: Conditions of AS approval so requires

- **Information to be provided in the national language:**
 1. Statement that the mixture/article incorporates biocides
 2. Biocidal property of the mixture/article (e.g. film protected against development of fungi, etc.)
 3. Name of all active substances and all nanomaterials (e.g. treated with [name of AS], incorporate [name of nano] as a nanomaterial, etc.)
 4. Instructions for use to protect man and environment, where appropriate (e.g. to protect the environment, the treated film cannot be used outdoor, etc...)

- **Outside these 2 cases:** Instructions for use to protect man and environment where appropriate (see point 4 above)

- **Obligation for suppliers to give some information at the request of a consumer within 45 days (i.e. similar to provisions in Article 33(2) of REACH)**

Application of the provisions on TA

- Provisions applicable since 1st September 2013, in particular concerning labelling provisions

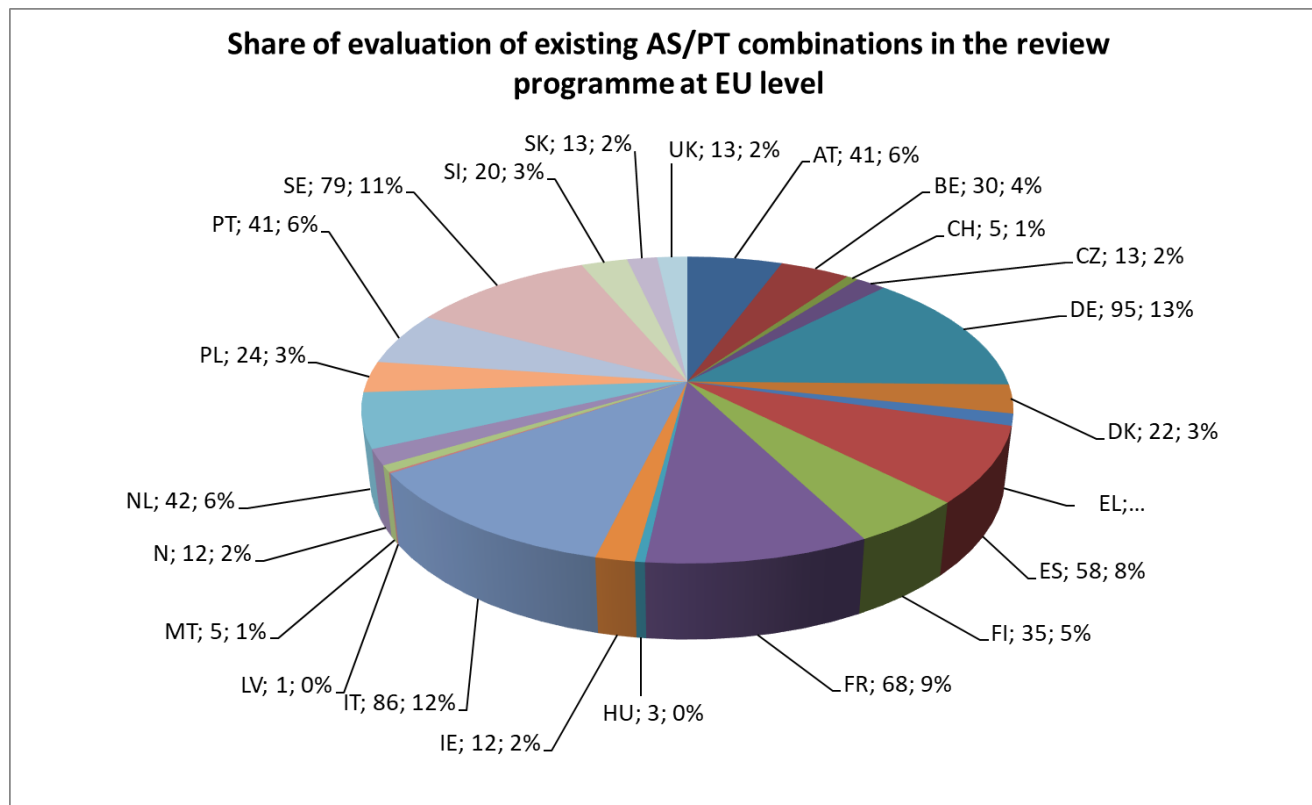
- **Transitional provision between 2013-2017 on active substances allowed (see Art. 94)**
 - **As from 1st March 2017:**
Only treated articles with active substances **approved, included in Annex I or under evaluation** on **1st September 2016** can *be placed on the EU market* (i.e. first supply, what is already in the chain of distribution can continue to be supplied)

- **Information on the ECHA website**
<http://echa.europa.eu/regulations/biocidal-products-regulation>

II – Status of in-can preservatives PT06 and film preservatives PT07

Organisation of the biocides framework

- Review programme of existing active substances : 2004 - 2024(?)
- 291 existing active substances (ie. present before 14th May 2000 on EU market) supported for one or several product-types = 727 dossiers



Examination process

The examination includes the following steps :

- Technical assessment by evaluating a Member State
- Peer review with all Member States organised by the European Chemicals Agency (ECHA) within its Biocidal Product Committee (BPC) to deliver its technical opinion on the properties, risks and efficacy of the active substance
 - ✓ For active substances subject to **exclusion** or **substitution**, a public consultation is organised to gather information on chemical and non-chemical alternatives :
<https://echa.europa.eu/public-consultation-on-potential-candidates-for-substitution>
- Decision making process at Commission level with EU Member States
 - ✓ For active substances subject to **exclusion**, a public consultation is organised to gather information on whether or not the conditions for derogation would be met :
<https://echa.europa.eu/derogation-to-the-exclusion-criteria-current-consultations>
 - ✓ Contributions: [CircaBC/SANTE/BPR - Public/Library/Active substances under exclusion - Public consultation on derogation](#)

Identification of alternatives during the review

- **Need for improvement on the identification of alternatives to AS subject to exclusion, substitution**
- Need better participation and input from stakeholders in public consultations (manufacturers, users, IND/NGOs etc.)
- Need for improvement of ECHA's BPC own input to get more valuable views on alternatives in the opinion, development of MS expertise:
 - To help the decision-making process on the AS
 - To facilitate BPs authorisation, and give indications to formulators of BPs and users of BPs on possible alternatives

Management of Review programme

- **Re-organisation of the Review Programme in 2014:**

Regulation (EU) No 1062/2014 depending of PTs (cf. Annex III)

Product-types	Time limits for MS to submit the assessment report to ECHA	Time limits for ECHA (BPC) to start the preparation of the opinion
8, 14, 16, 18, 19 and 21	31.12.2015	31.3.2016
3, 4 and 5	31.12.2016	31.3.2017
1 and 2	31.12.2018	31.3.2019
6 and 13	31.12.2019	31.3.2020
7, 9 and 10	31.12.2020	31.3.2021
11, 12, 15, 17, 20 and 22	31.12.2022	30.9.2023

- **Dates = Deadlines**

- **Delays in the review programme, actions for improvement :**

[CA-March18-Doc.5.1a - Final - Actions for AS review programme.pdf](#)

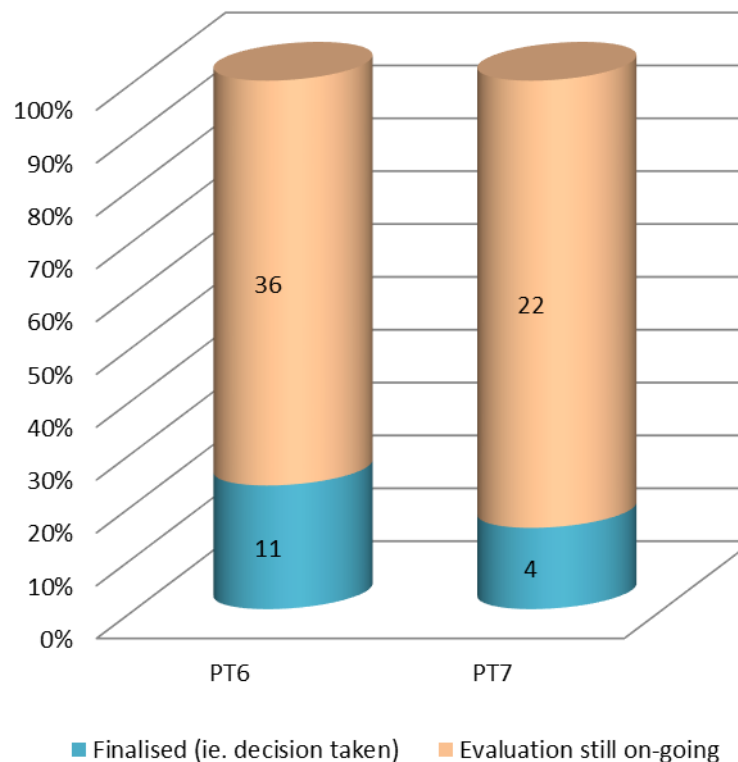
Progress on the review programme of existing active substances

- Overall, 33% of finalised evaluations in the whole review programme (i.e. decisions adopted)

More details :

- [CA-March19-Doc.5.1 - Progress of the RP of AS.doc](#)
 - [CA-May19-Doc.5.1 - Progress of the RP of AS.doc](#)
- **On PT06 : 23% finalised**
 - 47 AS in the RP
- **On PT07: 15% finalised**
 - 26 AS in the RP
- **Few applications for active substances outside the review programme (old existing, or new)**

Overall progress of the review programme of existing AS per PT



PT06 – PT7 Actives substances decisions

PT	RP (-) / Outside RP	Approval (A) /Non Approval (NA)	Name of AS	Duration of approval(in years)	Date of approval	Deadline year of submission of the application for renewal	Exclusion / Substitution	Comments	Provision on treated articles?
6	-	A	IPBC	10	01-07-2015	2023	No		Y
7	-	A	Tebuconazole	10	01-07-2015	2023	Substitution	Substance meeting the criteria to be vP and T	-
6	Outside RP	A	Folpet	10	01-01-2016	2024	No		Y
7	-	A	Folpet	10	01-10-2016	2025	No		Y
6	-	A	Glutaraldehyde	10	01-10-2016	2025	Substitution	Substance meeting the criteria to be classified Resp. Sens. 1	Y
7	-	A	Propiconazole	10	01-12-2016	2025	Exclusion	Substance meeting the criteria to be classified R1B	Y
6	-	A	Hydrogen peroxide	10	01-02-2017	2025	No		-
6	-	A	Formaldehyde released from MBM	5	01-04-2017	2020	Exclusion	Substance meeting the criteria to be classified C1B	Y
6	-	A	Biphenyl-2-ol	10	01-07-2017	2025	No		-
6	-	A	CMIT-MIT	10	01-07-2017	2025	No		Y
6	-	A	Peracetic acid	10	01-10-2017	2026	No		-
6	-	A	2-bromo-2-(bromomethyl)pentanedinitri le (DBDCB)	10	01-01-2018	2026	No		Y
7	-	A	Tolyfluanid	10	01-01-2018	2026	No		Y
7	Outside RP	A	Fludioxonil	10	01-04-2018	2026	No		Y
6	-	A	Chlorocresol	10	01-05-2018	2026	No		-
6	Outside RP	A	2-methyl-1,2-benzisothiazol-3(2H)-one (MBIT)	10	01-07-2018	2026	No		Y
7	Outside RP	A	Azoxystrobin	7	01-11-2018	2024	Substitution	Substance meeting the criteria to be vP and T	Y
6	-	NA	PHMB (1600;1,8)	-	-	-	Substitution	Substance meeting the criteria to be P and T	-
6	-	NA	PHMB(1415;4,7)	-	-	-	Substitution	Substance meeting the criteria to be P and T	-

Example of CMIT/MIT

- **Strong skin sensitizer with a low sensitization threshold, unacceptable risks identified for various uses, RMM to address these risks were identified**

- **Unanimous opinion from BPC on risks and RMM, one MS asking for further restriction:**
 - BPC opinion of February 2015 : <https://echa.europa.eu/documents/10162/a535466c-4c96-41eb-b532-38d6c54c7dc4>
 - Minority position from SE : <https://echa.europa.eu/documents/10162/64d529cf-f03a-4189-af2b-b707c380af09> , requesting identification as candidate for substitution : ie. comparative assessment of BPs, authorisation of BPs for 5 years...)

- **Approval Regulation 2016/131 of 1 February 2016, followed BPC recommendations**

In-can preservatives PT06

- **Concerns on availabilities of in-can preservatives raised since 2014 by IND stakeholders, in particular on**
 - Formaldehyde releasers : exclusion
 - Izothiazolinones : (strong) sensitizers

- **Bilateral discussions with IND, and in CA meetings :**
 - **58th CA of November 2014, 70th CA of March 2017 (+80th CA of September 2018)**
<https://circabc.europa.eu/w/browse/661e8fca-9353-47da-a031-c1341d6aa335>

- **Already in 2014, MSs :**
 - took note of the concerns
 - considered that the RP on PT06 AS ready for peer review could not be postponed
 - strongly invited IND to invest into R&D to find suitable chemicals and non-chemicals alternatives

Actions to promote substitution

- **EU level : CA note of September 2018:** [CA-Sept18-Doc7.4 substitution final.docx](#)
 - EU framework programme on research and innovation (Horizon Europe) : https://ec.europa.eu/info/designing-next-research-and-innovation-framework-programme/what-shapes-next-framework-programme_en
 - EASME/COSME project on substitution: <https://ec.europa.eu/programmes/horizon2020/en> ; https://ec.europa.eu/growth/smes/cosme_en
 - LIFE Programme: <https://ec.europa.eu/easme/en/life-programme>
 - Enterprise Europe Network : <http://een.ec.europa.eu/>
 - ECHA strategy to promote substitution to safer chemicals (2018): <https://echa.europa.eu/fr/-/new-strategy-promotes-substitution-to-safer-chemicals-in-the-eu>

- **Member States:**
 - Workshop on antifoulings (NL, October 2018)
 - Workshop on alternative rodenticides (DE, November 2018)
 - Other actions?

- **Industry? NGOs?**

III – The BPR and treated articles: the 2015’s agreement on labelling provisions

Labelling of TA in Approvals

- **Discussions in 2013-2015 on approval conditions related to labelling of TA**
 - **End 2014 – mid 2015 : various views, approvals blocked by MSs**
 - **Agreement : CA-May15-Doc.6.1 - Final (<https://circabc.europa.eu/w/browse/f35afe61-e165-4171-a752-6278d71ac63e>)**
 - **Systematic requirements of the specific labelling provisions of Article 58(3) of BPR when :**
 - ❖ A specific use is fully restricted
 - ❖ The substance meets the exclusion criteria set in Article 5(1) of BPR (CMR, PBT, ED), but is nevertheless approved
 - ❖ The substance have the following intrinsic properties :
 - ❖ Skin sensitizer category 1 or sub-category1A
 - ❖ Respiratory sensitizer
 - ❖ vP or vB
 - ❖ P and B
 - ❖ SVHC identified under Article 57 of REACH
 - **Provision on approval :**

"The person responsible for the placing on the market of a treated article treated with or incorporating [the active substance X] shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012"

Labelling of TA in Approvals

- **Re-discussed at a couple of occasions at the request of IND, in particular to apply the measure only to articles and not mixtures**
 - **In CA meetings in 2015-2016**
 - Conclusion: no change of approach, no need for distinction between articles/mixtures, labelling not disproportionate, limited and reasonable information requested on the label, complementary to CLP
 - **Proposal submitted by CEFIC via the REFIT platform in 2017 to ask for the drop of the labelling measure on mixtures**
 - Not supported by the REFIT platform members, and finally withdrawn (2018)
- **Labelling principles remain as agreed by CAs in 2015**



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Conclusion

- **Upcoming decisions in the next years on the approval of in-can and film preservatives**
- **Key expectations of society and principles of the legislation on safety, exclusion/substitution won't disappear**
- **As required by the BPR, risks must be addressed**
- **EU actions to support R&D**
- **MS actions?**
- **In any case, key role of IND and actions needed:**
 - Meet the societal and regulatory expectations
 - Need for innovation and increased investments in R&D

Thank you for your attention

For further information:

Commission website:

http://ec.europa.eu/health/biocides/policy/index_en.htm



<https://circabc.europa.eu/w/browse/e947a950-8032-4df9-a3f0-f61eefd3d81b>

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ECHA website & Helpdesk on Biocides:

<http://echa.europa.eu/regulations/biocidal-products-regulation>