

Control of treated articles in the Biocidal Products Regulation

ECHA Biocides Stakeholders' Day 25 June 2013

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Treated articles Why regulate?

- Consistency between articles treated within and outside EU in terms of
 - protection of health and environment, and
 - competition
- Better control of the use of treated articles
- Better information to users







Treated articles What are they?

Definition of "treated articles":

- Substance, mixture or article, i.e., not only articles within the meaning of the REACH Regulation
- Treated with or intentionally incorporating biocidal products

Excluded from the substantive rules:

Container fumigation where no residues remain



Treated articles What can we sell?

Conditions for placing on the market

- All the active substances have to be approved for the relevant product type and use
- Article has to comply with any relevant conditions of approval of the active substance



Treated articles Transitional rules

Substance/product-type combinations that have not yet been approved are allowed if

- The substance/product-type combination is still in the review programme, or
- An application for approval is submitted before 1 September 2016



Treated articles Un-intended market freeze during transition?

The problem

- Transitional rules apply to 'treated articles that were available on the market on 1 September 2013'
- So, what if I want to introduce a new car model...?

The solution

- Commission proposal to amend BPR,
 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2013:0288:FIN:EN:PDF
- Inclusion of new treated articles in transitional rules, pending decision on approval of the active substance



Treated articles

What is a "use" permitted by the substance approval?

- Proposed to mean any use covered by the product-type in question, except where explicitly restricted
- Specific uses of treated articles may be restricted in substance approvals where problem identified in substance evaluation
 - *C.f.* use classes in approvals of wood preservatives
- Special conditions for specific hazards or critical effects
 - E.g. substances fulfilling exclusion criteria, food contact materials



Treated articles What must we tell?

- Obligation for suppliers to give some information at the request of a consumer within 45 days
- Labelling is required if
 - Claim is made regarding biocidal properties of the article, or
 - Conditions of substance approval so require
- Information to be provided in the national language
 - Statement that article incorporates biocides
 - Biocidal property of the article
 - Name of all active substances and all nanomaterials
 - Instructions for use to protect man and environment, where appropriate
- Instructions for use, on any article where necessary to protect man or environment



Treated articles considered biocidal products

Treated articles having 'primary biocidal function' (Article 3(1)(a))

- Biocidal function = the function of controlling harmful organisms by other than mere physical or mechanical action
- Biocidal treatment for preservation of the article itself ≠ biocidal function
- Primary = of first rank or importance compared with another function
- Concept to be clarified on case-by-case basis (Article 3(3))
- Criteria under discussion (intended use, claim regarding the function, concentration of active substance)



Treated articles More issues open to interpretation

- 'Biocidal property' triggering labelling requirement?
- Complex articles of which only parts have been treated?
- Communication obligations further down the supply chain?
- Level of scrutiny of different uses of treated articles for the purpose of active substance approval?
- Draft Commission guidance on treated articles:

https://circabc.europa.eu/w/browse/a9c802ed-f80d-40c7-b113-3a6d03b2f87c



Thank you for your attention!

For further information:

Commission website on biocides:

http://ec.europa.eu/environment/biocides/

CIRCABC public space for 'biocides CA meeting':

https://circabc.europa.eu/w/browse/661e8fca-9353-47da-a031c1341d6aa335

ECHA website & Helpdesk on Biocides :

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