The tricky rules for Treated Articles:

Ulrike Frank

Biocides Stakeholder's Day, Helsinki

26.-27. September 2017



Content

- What is a treated article and what is not?
- Obligations connected with treated articles
 - For the purpose approved substances
 - If a claim is made....
- What is a biocidal function?
- What is a claim?
- Consumer information

Treated articles – new kids on the block

- Treated articles first time regulated with Biocidal Products Regulation (BPR) from 1. September 2013
- What is a treated article?
 - anything treated with a biocide

But.....

What is not a treated article?

- If the treated article has a <u>primary biocidal function</u>, it is a
 - Biocidal product!
- If the treated article is a mixture and has a biocidal function, it is a
 - Biocidal product!

What is not a treated article?

- If the treated article contains (small) leftovers from a production process and the biocidal function was only intended for the production process, it is
 - Out of Scope (i.e. not regulated by the BPR)

Note: This is an interpretation of a guidance document

What is a treated article?

- An article which as a whole or of which parts have been treated with a biocide with the intention to impart a biocidal function to the article or parts of the article
 - To protect the article/material from deterioration, or
 - To protect humans or animals using the article from unwanted effects of harmful organisms

What are the obligations for treated articles?

- When articles are treated with biocides, only for the purpose approved active substances may be used
- If a claim is made
 - To label the product with information on the active substance, what biocidal property the article has, instructions for use, precautonary measures, etc.
- Consumers have to be provided on request with the information about the biodical treatement of the article

For the purpose approved active substances

What does this mean?

- During substance approval, the purpose of the treatment has to be stated and tests which demonstrate efficacy for that purpose have to be provided.
- the substance needs to be approved for the right PT*
- the substance needs to be approved for the right use*

^{*}see Art. 58(2) BPR

For the purpose approved active substances?

Example1:

A substance is approved as a PT 6 (in-can-preservative).
 It must not be used for applications where the dry paint needs to be protected (e.g. house facades, PT 7), or where humans need to be protected (e.g. from mold on walls, PT 2)

For the purpose approved active substances?

Example 2 (from HelpDesk):

- Copper is under review in PT 2. The approved use is as a ionisation system with the purpose to disinfect liquids (e.g. swimming pools, spas).
- Copper shall be used in pulverised composite materials, applied to objects (e.g. door handles) to protect users from bacterial contamination (PT 2)
- → this use is different, it has not been assessed during substance evaluation and is not approved

If a claim is made....

What is a claim? Basically, any statement that the article has a biocidal function.

What is a biocidal function?

 the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action. (Art. 3a)

....biocidal function requires:

- 1. A chemical is involved
- 2. Intention
- 3. The damage is caused by harmful organisms



Is a chemical involved?



2



Is there intention to destroy?



3



Is the damage (bad smell) caused by harmful organisms?



ocidal product

...a claim is made

Examples

- Durable mildew and algae resistance (facade paint)
- Anti-odour, neutralizes bad odour, anti-odour-technology, odourless, etc. (sportswear)
- Antibacterial, reduces the spreading of bacteria, removes xx% bacteria, bacteria-resistent, antimicrobial, etc. (any article)
- Preserves, protects, impregnates (wood preservative)
- Pressure treated, impregrated (wood)

Mixtures with biocidal functions

....are biocidal products!







When does a claim not trigger BPR-requirements?

 ... when the biocidal function is not caused by an added chemical preservative/disinfectant

Example: certain clothes (wool, bambus, etc.) which are claimed to be "naturally antibacterial"

- ...when the damage being prevented/cured is not caused by organisms
- ...when the claim is based on a mechanical action

If a claim is made...

...labelling obligations follow. These include:

- statement that the article incorporates biocidal products
- The biocidal property attributed to the article
- > The (chemical) name of all active substances
- Possible nanomaterials contained (their name)
- > Instructions for use, including precautions

In case of "silent treatement" (example in-can preservatives) no labelling is necessary.

www.kemi.se

Consumer information on request

OBS: concerns all treated articles, also "silently"-treated ones

- The supplier has to provide information on biocidal treatment, on request, within 45 days*
- Precondition: Information on biocidal treatment (why, what, how?) has to be handed down the supply chain.

*Art. 58 (5)

Market survey on articles treated with biocides

(<u>www.kemi.se</u>: PM 6/16)

- Scope: To find out whether the provisions for treated articles are followed by market participants
 - 1. Are TA labelled correctly if a claim is made?
 - 2. Is information to consumers given on request?
 - 3. Do Member States Competent Authorities agree how to interpret the rules?

Conclusions

- Distinction between treated articles, biocidal products and articles out of scope is important but complex.
- Only active substances approved for the right PT and use are permitted in TA.
- A claim triggers labelling obligations; important to know about the organisms which cause the damage which shall be prevented and about the effect of the BP used (on target and non-target organisms).
- This information is also necessary to inform consumers on request.