CEPE guidance "Labelling of Treated Articles"

WARNING: This subject is still under discussion at EU level and could be adapted following a new and agreed interpretation, in which case the guidance will be amended accordingly.

Introduction

The BPR (Biocidal Product Regulation 528/2012), published on 27 June 2012, is the new Regulation replacing the BPD (Biocidal Product Directive 98/8/EC). It will apply on 1 September 2013 though some provisions are subject to transitional periods.

One of the changes introduced by the BPR is the extension of its scope to treated articles.

The definition is the following (Art 3)[1]:

> *'treated article' means any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products*

The BPR also includes substances and mixtures as potential 'treated articles'. Hence, as explained in the examples below, many CEPE Members products will fall under the BPR definition of treated articles and new obligations derive from it.

Its Article 58 introduces new obligations for the placing on the market of "Treated Articles". This Industry Guidance document focuses on point 3 of the Art 58, which describes the labelling requirements of Treated Articles under certain conditions. Two additional topics related to treated articles are covered in the Annex.

CEPE Members are generally users of biocides as Product Type PT6 (in-can preservatives), PT7 (dry-film preservatives) or PT 10 (masonry preservatives). Some are also involved in PT2 (disinfectants), PT8 (wood preservatives), PT18 (pest control) and PT21 (anti fouling) activities.
The first important differentiation is to be made between "biocidal product" and "treated article". It should be noted here that the BPR considers that a product that has a primary biocidal function shall be considered a biocidal product.
The second important aspect to understand is when a treated article has to be labelled.
This document aims at clarifying the subject for CEPE Members.

[1] In REACH: Registration, Evaluation and Authorization of Chemicals, Regulation 1907/2006, an article is defined as "an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition".

Biocidal product or treated article?

The definition of a biocidal product that has been applied up to now under the BPD (1998/8) remains on the whole valid. Basically, the claim[2] is of key importance. Under the BPD as soon as a claim was made for an external biocidal effect, the product became a biocidal product. Under the BPR the term 'internal effect' or 'external effect' is not employed anymore, rather the key criterion is whether a treated article has a 'primary biocidal function'. What 'primary' means is still subject to debate and is not of key importance for CEPE to understand whether you place on the market a biocidal product or a treated article.

Examples:

1. I use a bactericide to protect my water based paint or my printing ink[3] against microbial deterioration in the wet stage (in the can). There is no external claim. The bactericide is used solely to protect the paint. The paint is not a biocidal product, but is a treated article.
2. I use a fungicide to protect the dry film against discoloration. The fungicide is used to protect the film itself => the paint is protected. There is no 'external claim' or 'primary biocidal function' made. The paint is not a biocidal product, but is a treated article.
3. I use an algaecide to protect my cement based plaster used to finish a facade, same situation as in 2.
4. I use a bactericide at relevant concentration to provide an external effect (a 'primary biocidal function') that I claim, such as for an anti-bacterial paint used in hospitals. My claim is linked to a better health hygiene to prevent the development of microbes on the surface of the walls. The claim is linked to Human Health effect. Because the claim is for an external effect (the bactericide is used not (solely) to protect the paint but to have an effect of a nature outside the paint), the paint IS a biocidal product and needs to be authorized under the BPR for PT2.
5. Same as in 4, I intend to use an insecticide to incorporate into a paint with the claim (a 'primary biocidal function') that it will control flies. The insecticide is obviously not present to prevent insects to damage the dry-film and the mixture falls under the need to authorize the product under the BPR for PT18.
6. I use a fungicide in a wood coating with the claim that it will prevent rotting of the wood. I make a claim for an outside effect (i.e. by using the fungicide in the coating I will protect the wood underneath). The coating is a biocidal product, a real wood preservative product (PT8) that has to be authorized, and the claim must be supported by the relevant efficacy data (such as EN 113).
7. I use a fungicide in a wood coating with the claim that it will prevent blue stain of the wood. The blue-stain claim is to be substantiated by an EN 152 standard test that requires a minimum penetration in the wood. Success in passing the test will put me in a biocidal product category (wood preservation PT8). A failure to pass the test would indicate that I cannot make such wood preservation claim, in which case my claim could be limited to film protection and the coating becomes a treated article.

Now that everyone understands the difference between biocidal product and treated article, we will in the next pages address the issue of the labelling of treated articles..

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[2] NB : be careful that a claim made in other documentation than the label, such as a Technical Data Sheet, or promotion in any form, such as on internet, would also be regarded as a relevant claim by the controlling Authorities

3 The BPR shall not apply to biocidal products or treated articles that are within the scope of a number of instruments, including cosmetics (1223/2009) and toy safety (2009/48)

Labelling of treated articles

Once you know that you are placing on the market a treated article (because you have used a biocide – your product was treated with or intentionally incorporates a biocidal product), the next question is: when do you have to label it?

The Article 58 (3) states:

> *3. The person responsible for the placing on the market of such a treated article shall ensure that the label provides the information listed in the second subparagraph, where:*
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> *- in the case of a treated article containing a biocidal product, a claim is made by the manufacturer of that treated article regarding the biocidal properties of the article, or*
>
> *- in relation to the active substance(s) concerned, having particular regard to the possibility of contact with humans or the release into the environment, the conditions associated with the approval of the active substance(s) so require.*

There are therefore two situations that require labelling:

Condition 1: you make a claim regarding a biocidal property. Again you have to carefully understand the consequence of making a claim. The term 'property' must be differentiated from the term 'function'. A product that has a primary biocidal function must be regarded as a biocidal product, but a treated article may still contain biocidal products that deliver a certain property to the article. According to the current draft of the European Commission's guidance on treated articles, a 'property' is a characterizing quality. However, a 'function' refers more specifically to the intended purpose of a product.
Example 1: the incorporation of a dry-film preservative biocidal product in a coating does not make the coating a biocidal product (see above, no external claim) but provides the coating with the property that it is protected against certain discoloration/disfigurement. If you make a claim of the type 'this paint is protected against disfigurement caused by fungi and algae', then you will fall under condition 1 and you will have to label (see below for the label requirements).
Example 2: you use an in-can preservative to protect your water based paint. Of course you do not claim that it is protected for microbial deterioration, it is obvious since without doing so the first customer would run away from your product once opening the can... In this case you would not need labelling.

Condition 2: this is not within the control of CEPE Members, but depends on the outcome of the BPD/BPR assessment of the relevant active(s) and cannot be predicted today[4]. This condition means that if the outcome of the risk assessment for the use of the relevant active(s) in coatings would have demonstrated some remaining concerns (for Human Health and/or for the Environment), then the end-use product (your coating) will have to warn the user of certain dangers/risks/risk mitigation measures and comply with the labelling elements of Art 58(3) outlined below.
Here we can only advise CEPE Members to ask their biocide suppliers to keep them up to date as possible issues coming out of the evaluation of their active(s) may be raised, and in

4 Of course the question is always: 'When do we expect the revision of existing actives to be finalised?' Initially it was May 2010, then it became May 2014 and today the EU Commission got another postponement up to 2025.

parallel do their own assessments as soon as documents become publicly available. This is the more relevant because, once certain negative decisions will be made on the use(s) of active(s), there will be limited time available to place the products on the market.

Labelling requirements

Art 58(3) states the following:

> *The label referred to in the first subparagraph shall provide the following information:*
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> *(a) a statement that the treated article incorporates biocidal products;*
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> *(b) where substantiated, the biocidal property attributed to the treated article;*
>
> *(c) without prejudice to Article 24 of Regulation (EC) No 1272/2008, the name of all active substances contained in the biocidal products;*
>
> *(d) the name of all nanomaterials contained in the biocidal products, followed by the word 'nano' in brackets;*
>
> *(e) any relevant instructions for use, including any precautions to be taken because of the biocidal products with which a treated article was treated or which it incorporates.*

Some explanations:

(a) Such statement could be as simple as 'This paint contains a biocidal product'.
(b) This could be included in the previous phrase and read 'This paint contains a biocidal product for the preservation of the dry film'. The location of the claim is not specified in the BPR; therefore it does not need to be placed next to the other labelling requirements. This is also true for the other labelling requirements that can be placed in different locations. Hence it does allow some flexibility. For instance, when paints are sold in pre-printed cans we would not want to have to change the labelling requirements when another biocidal product is used. Example: you switch the dry-film preservative from a product containing a certain fungicide active to another one. This requires changing the naming of the active. If this is placed on pre-printed cans the stock would have to be destroyed or a sticker placed on the label. In that situation the naming of the actives should be placed on another document accompanying the sale of the paint. On the other hand a typical precaution could be 'do not apply above surface waters like ponds or rivers', and this would be applicable to both fungicides actives so it could be placed on the can.
(c) This requires the naming of the actives used (only the actives that are linked to the claim or approval conditions; i.e. if the claim is for dry-film preservation the in-can actives in the product do not need to be mentioned), such as 'IPBC (CAS 55406-53-6) and terbutryn (CAS 886-50-0)'. CEPE advises to add the CAS numbers in order to allow an easy identification of the substances, which is not always possible with chemical names.
(d) This does limit the requirement to state nano forms of biocide actives linked to the biocidal property claim such as 'contains (nano) silver'
(e) Typically this should come from the outcome of the evaluation of the biocide products, when they will be authorized under the BPR and when such requirement would specifically apply. Example: 'Do not apply near or above surface waters like rivers or ponds'

You have understood that making a label claim requires new labelling provisions, the impact of which should not be underestimated.

Other obligations for treated articles:

> Art. 58.5 : *Notwithstanding the labelling requirements set out in paragraph 3, the supplier of a treated article shall, where a consumer so requests, provide that consumer, within 45 days, free of charge, with information on the biocidal treatment of the treated article*

In the absence of more accurate information on what precisely has to be communicated, it is recommended to obtain a legal opinion.

Deadline for complying with the labelling requirements of Article 58 (3)
The legislator has not foreseen the need to have a transitional period, so the requirements apply from 1 September 2013. This is valid for treated articles that are placed on the market from that deadline. According to the latest draft guidance from COM (tabled at the May 2013 CA meeting), the labelling requirements for treated articles already on the market before that date do not apply.

We recognize that compliance by that date is going to be very challenging for CEPE members, especially if pre-printed cans are used, but CEPE advises members to try complying as soon as possible.

Annex

Other obligations for treated articles:

Art 58(2): Treated articles shall only use approved biocide actives for the supported Product Types (from which derive the uses).
The European Commission will draw up a Union list of approved biocide active substances (Art 9(2)).

Art 95 on approved suppliers. The EU Commission is going to publish a list of approved active substance suppliers by 1 September 2013 and this list will be updated when new suppliers shall be added[5].
By 1 September 2013 only approved biocide suppliers will be able to place on the market biocide actives.
Two years later, by 1 September 2015, biocidal products can only be placed on the market if they contain a biocide active from the approved supplier list. Disposal and use of existing stocks of biocidal products containing actives coming from non approved suppliers can then continue until 1 September 2016.
Hence, the manufacture of treated articles in Europe can only be made using biocidal products containing actives coming from approved suppliers, by 1 September 2016 latest.

Deadlines for the placing on the market of treated articles (Art 94)

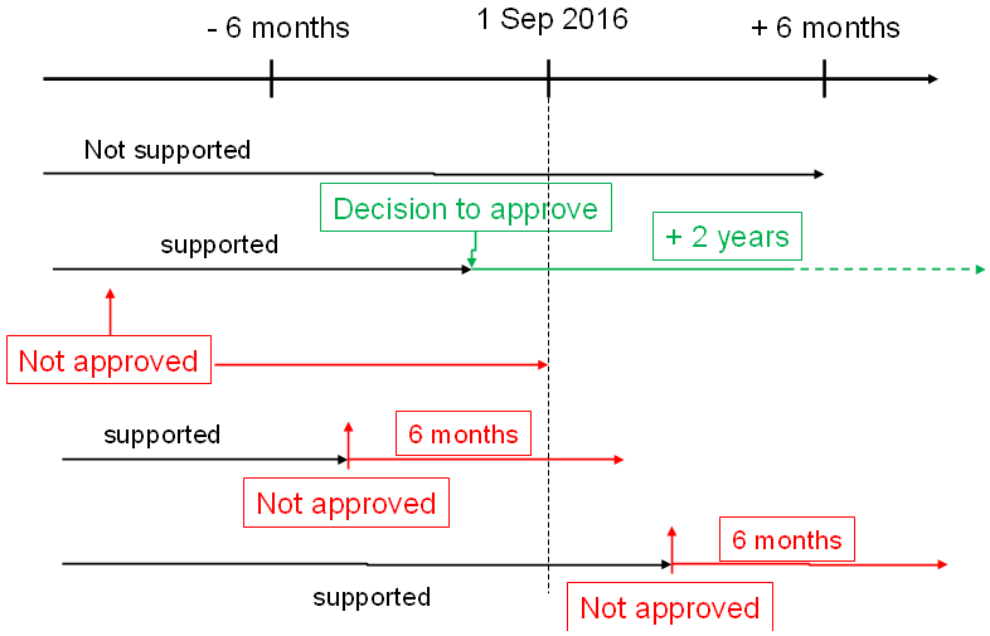
This section concerns the deadline for placing on the market treated articles when an active substance/Product Type/use combination is not supported anymore or when a negative approval decision has been made.

Due to the transitional measure linked to the implementation of this new BPR provision of treated articles, the important deadline is situated around 1 September 2016. In the future, it is important to note that treated articles must no longer be placed on the market 180 days after a non approval decision for an active substance contained in the biocidal product used to treat or intentionally incorporated in those treated articles. This is going to be the key date to follow for each relevant active/PT. Again we encourage CEPE members to be vigilant in the future.

The situation can be summarized as follows:

NB: “supported active” means an active that is supported by Industry (biocide supplier(s)) and is being reviewed under the BPD/BPR. “Not approved“ means that Authorities refused granting authorisation or that Industry stopped supporting the dossier.

[5] Note that it is expected that some new suppliers will use the forced data sharing provisions of the BPR to become approved suppliers in the following years. This does not by all means mean that suddenly it becomes easy for new interested suppliers to be recognized since it is expected that significant money will be required to be able to supply a full dossier (either on its own or through data sharing and letters of access).



Examples:

1. I am currently placing on the market a paint that was made outside Europe and that contains an in-can preservative that is not supported under the BPD since 2006. The deadline for continuing such import (without prejudice to other legislations that may apply, such as REACH) is 1 September 2016 + 180 days.
2. 1 May 2016, a non-approval decision for the active that I am using in my paint is made: I have 6 months to cease the placing on the market[6], i.e. 1 November 2016.

6 Placing on the market: the first making available on the market.
Making available on the market: any supply for distribution or use in the course of a commercial activity, whether in return of payment or free of charge.