CEPE guidance note "Labelling of Treated Articles" revision 3

November 2016

Guidance History:
Original version: May 2013
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Revision 3: November 2016

The main reason for the first update was linked to the final position that the EU Commission took in May 2015 on the labelling conditions for treated articles into the biocide active substance approval Regulations.
Because our members met difficulties in complying with both the CLP and the additional labelling provisions of the BPR, the second revision added practical examples to comply with both labelling requirements for skin sensitizers.
This version three includes a few relevant comments on these examples that were made following the issuance of the October 2016 version to avoid any misunderstanding on this complex issue.

Introduction

The BPR (Biocidal Product Regulation 528/2012), published on 27 June 2012, is the Regulation replacing the BPD (Biocidal Product Directive 98/8/EC). It applies since 1 September 2013. 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 also related to treated articles, but not related to labelling issues, 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.

[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".

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 (such as an anti-fouling paint).
The second important aspect to understand is when a treated article has to be labelled, and this can take place in two occasions: 1) once a biocidal **property** is claimed, and 2) if the **approval conditions of the active substance** requires specific provisions for treated articles. This document aims at clarifying the subject for CEPE Members.

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

[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)

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.

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:*
>
> *- 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:

Situation 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. 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 situation 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 according to situation 1, but you may need it according to situation 2.

Situation 2: in May 2013 we were writing: '*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.*

The situation has now evolved as the EU Commission with the support of Member States

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.

finally agreed in November 2015 that labelling provisions will apply for **all skin sensitizing substances classified as category 1 or 1a** (which means most of them as few are only 1b) [5].
They have now started to include a standard provision in the approval regulation of these substances (see the example of CMIT/MIT PT6 No 131/2016):

> *The person responsible for the placing on the market of a treated article treated with or incorporating C(M)IT/MIT (3:1) 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.*

It must be pointed out that there are other hazard based classification criteria that will also trigger the labelling requirements: vP or vB, P and B, respiratory sensitizers, other substances identified as SVHC under REACH (could be due to endocrine disruptive effects or specific organ target toxicity etc.), and also if a use is restricted or if the active fulfils the exclusion criteria. It is expected in practice that skin sensitizers will be the substances that will mostly trigger such new labelling requirements.

It must also be highlighted that when COM started to add labelling requirements to substance approvals back in 2013 they only targeted skin sensitizers (and not PBT etc.) and made specific reference to it in the legal texts. Hence the paragraph that was added in the approval regulations of a few substances contained specific reference to skin sensitization as per the example of IPBC for PT6 (Regulation 1037/2013):

> *'Where a treated article has been treated with or intentionally incorporates IPBC, and where necessary due to the possibility of skin contact as well as the release of IPBC under normal conditions of use, the person responsible for placing the treated article on the market shall ensure that the label provides information* ***on the risk of skin sensitisation****, as well as the information referred to in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012'*

As a consequence the labelling requirements for some substances may slightly differ due to the specific need to add reference to skin sensitization.
In the case of IPBC it must be highlighted that when it was approved for PT8 in 2008 no labelling provision existed, and when it was approved for PT13 in 2015 the labelling requirement did not anymore contain indication on the risk of skin sensitization. This is somewhat confusing and it shows the change of thinking of the Authorities throughout the years.

Important note: this condition for skin sensitization does not involve any threshold concentration. Hence, as soon as you intentionally add a biocide that meets one of these criteria in your product, the new labelling provisions apply. This also means that the biocide that your raw material supplier added to preserve his own product does not fall in scope (at a relevant concentration to preserve that product and not at higher concentration that would preserve your own product).

[5] For further details see the EU COM document CA-May-15-DOC.6.1-final 'Labelling of treated articles'

Labelling requirements
Art 58(3) states the following:

> *The label referred to in the first subparagraph shall provide the following information:*
>
> *(a) a statement that the treated article incorporates biocidal products;*
>
> *(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. The question is what chemical name should be used? In order to save label space CEPE advise to use the shortest abbreviation possible, but still legally justifiable. See below under 'General principle for naming substances in products' for further explanation.
(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'

Hence, Art 58(3) of the BPR contains 5 requirements under (a) to (e) but not all are relevant for us.

- For in-can preservation PT6 it is expected that the sole relevant requirement is in (a) and (c): a statement that the TA contains a biocide (or more than one).
- For dry-film preservation PT7 the property must be added in addition (according to (b)).

Specific instructions for the point (e) might also come in the future (particularly for PT7), depending on the approval conditions of biocidal products (mixtures).

Practical recommendations to implement the BPR labelling requirements in addition to the CLP requirements.

When we issued the revised guidance (version 1) in February 2016, members expressed difficulties to identify the relevant names of biocide substances to use and to combine the CLP and the BPR sentences when skin sensitization is involved. This section provides guidance to members on those aspects.

Warning: the information provided below has been developed to facilitate the implementation of the labelling requirements as much as possible. However, members may have to adopt this based on own considerations (IT system, customer expectations…).

1. General principles for naming substances in products

ECHA labelling and packaging guidance recommends following the hierarchy in CLP Article 18(2) for naming of substances in mixtures (Annex VI name; C&L inventory name; other internationally recognised name e.g. INCI nomenclature), but states that it is preferable to use the name that is most well-known to the user/consumer, which is likely to be a shorter name. Also, if a substance has to be named on the label under both CLP and other legislation, the same name should be used for both.

The labelling requirements of BPR Article 58(3) require BPR names to be used. These are published in the approval regulations for the active substances.

CEPE recommends using the abbreviation for a biocide if given as the name in the official approval regulation. Otherwise use the shortest name available, typically the INCI name.

Examples:

- **C(M)IT/MIT (3:1)** is used in Regulation 2016/131
  (CLP Annex VI name: reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1))

- **IPBC** is used in Regulation 1037/2013
  (CLP Annex VI name: 3-iodo-2-propynyl butylcarbamate).

- **Methylisothiazolinone** in INCI/EU Cosmetics Glossary
  (C&L inventory: 2-methyl-2H-isothiazol-3-one; PT13 approval regulation: 2-methylisothiazol-3(2H)-one).

2. General principles for combining CLP and BPR labelling

CEPE recommends avoiding duplication and reducing the information on labels to a minimum as far as possible. Some principles for this:

- If a product contains several substances requiring EUH208, include all names in the same statement.
- If a product contains several biocides to be named according to BPR Art. 58(3) (point (c)), include all names in the same sentence.
- If a biocide requires both of the above, avoid duplication by using the first part of EUH208 to cover the naming of the active substance(s).
- If the approval regulation requires identification of a specific risk, such as skin sensitisation, include short text for this at the end of the phrases **if** not already covered by EUH208 or other (supplemental) hazard statements.

NB: if a biocidal active substance is not yet approved, use CLP labelling elements only (e.g. EUH208).

3. Examples for single active substance under the following situations:

Note: the examples below contain substances that have not yet been approved for the relevant PT, hence the BPR labelling requirements do not yet apply to them (such as for MIT and BIT for PT6) but have been used to clarify the various possibilities. Although we do not expect that the standard paragraph added for skin sensitizing substances in their approval regulations will change, it will be important to check this upon their publication.

a) Concentration leading to classification of the mixture: apply H317
DCOIT in wood paint >250 ppm (250 ppm today according to supplier. In future may be lowered (since Norway proposed 10 ppm)).
The product is classified as skin sensitizer and the hazard statement "**May cause an allergic reaction**" must appear on the label. The name of the substance must also be given due to BPR Article 58(3) and CLP Article 18(3): "**Contains 4,5-dichloro-2-octyl-2H-isothiazol-3-one."**

b) Concentration leading to EUH 208 and substance/PT not yet approved: apply EUH 208 only
MIT used in paint as PT6. 100 ppm today for EUH 208 according to supplier. RAC Committee decided on 15 ppm for induction (= 1.5 ppm for EUH 208). To be officially published with ATP in future. Decision to classify already at 15 ppm to be made.
>100 ppm: "**Contains methylisothiazolinone. May produce an allergic reaction**."

c) Concentration leading to EUH 208 and substance/PT approved: apply EUH 208 and Art 58(3)
Example 1: IPBC used in paint as PT6. >1000 ppm and <10000 ppm:
"**Contains a biocidal product: Contains IPBC. May produce an allergic reaction**."

Example 2: CMIT/MIT used in paint as PT6. >1.5 ppm and <15 ppm:
"**Contains a biocidal product: Contains C(M)IT/MIT (3:1). May produce an allergic reaction**."

d) Concentration below EUH 208 and substance/PT not approved: no labelling info needed
-

e) Concentration below EUH 208 and substance/PT approved: apply Art 58(3)
<1.5 ppm: "**Contains a biocidal product: C(M)IT/MIT (3:1)**"
<50 ppm: "**Contains a biocidal product: BIT**"
<1000 ppm: "**Contains a biocidal product: IPBC. Risk of skin sensitization**"

4. Examples for multiple active substances under the following situations:

Note: the examples below contain substances that have not yet been approved for the relevant PT, hence the BPR labelling requirements do not yet apply to them (such as MIT and BIT for PT6 or IPBC for PT7). Although we do not expect that the standard paragraph added for skin sensitizing substances in their approval regulations will change, it will be important to check this upon their publication.

a) A substance triggers H317, another one EUH 208, and a third one is <EUH 208

DCOIT >250 ppm + BIT between 50-500 ppm + CMIT/MIT <1.5 ppm:

DCOIT drives H317 classification + BPR Art 58(3) (a) + (b)
BIT adds the substance name (CLP Annex II 2.8) + BPR Art 58 (a)
CMIT/MIT requires BPR Art 58(3) (a) + (c)

b) A PT6 substance requires EUH 208 and a PT7 substance claims a biocidal property under EUH 208

CMIT/MIT at 10 ppm for PT6 + IPBC at 900 ppm for PT7 (with claim):

CMIT/MIT needs EUH 208 + BPR Art 58(a)
IPBC needs BPR Art 58(a) + (b) + (c)

"**Contains a biocidal product: Contains C(M)IT/MIT (3:1). May produce an allergic reaction. Contains a biocidal product for the preservation of dry-film: IPBC**"[6]

c) Two PT6 substances require EUH 208 and a PT7 substance claims a biocidal property below the level for EUH 208

CMIT/MIT at 10 ppm for PT6 + BIT at 400 ppm + IPBC at 900 ppm for PT7 (with claim):

CMIT/MIT and BIT need EUH 208 + BPR Art 58(a)

[6] NB: for IPBC reference to skin sensitization is normally not going to be made in its future PT7 approval, it was done only for PT6.

IPBC needs BPR Art 58(a) + (b) + (c)

"**Contains a biocidal product: Contains C(M)IT/MIT (3:1) and BIT. May produce an allergic reaction. Contains a biocidal product for the preservation of dry-film: IPBC** *(see also footnote 6)*"

d) A PT6 substance requires EUH 208 + another PT6 substance is under EUH 208 + a PT7 (with claim) substance also under EUH 208

CMIT/MIT at 10 ppm for PT6 + IPBC at 900 ppm for PT7 (with claim) + BIT at 40 ppm for PT6 (when it is approved in an official Regulation under the BPR):

CMIT/MIT needs EUH 208 + BPR Art 58(a)
IPBC needs BPR Art 58(a) + (b) + (c)
BIT requires BPR Art (58) (a) + (c)

"Contains a biocidal product: Contains C(M)IT/MIT (3:1). May produce an allergic reaction. Contains a biocidal product: BIT Contains a biocidal product for the preservation of dry-film: IPBC."

Deadline for complying with the labelling requirements of Article 58 (3)

For condition 1: the legislator had not foreseen the need to have a transitional period, so the requirements applied from 1 September 2013. This is valid for treated articles that are placed on the market from that deadline.

For condition 2: the date of approval of the active substance for the relevant PT (this is typically 18 months after the date of publication of the approval regulation).

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 status of approval of active substances can be consulted on the ECHA website here:
http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances

Art 95 on approved suppliers.
By 1 September 2013 only approved biocide suppliers were able to place on the market biocide actives. Two years later, from 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.
The list of approved suppliers can be found here:
http://echa.europa.eu/web/guest/information-on-chemicals/active-substance-suppliers

Article 58.5

> 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.

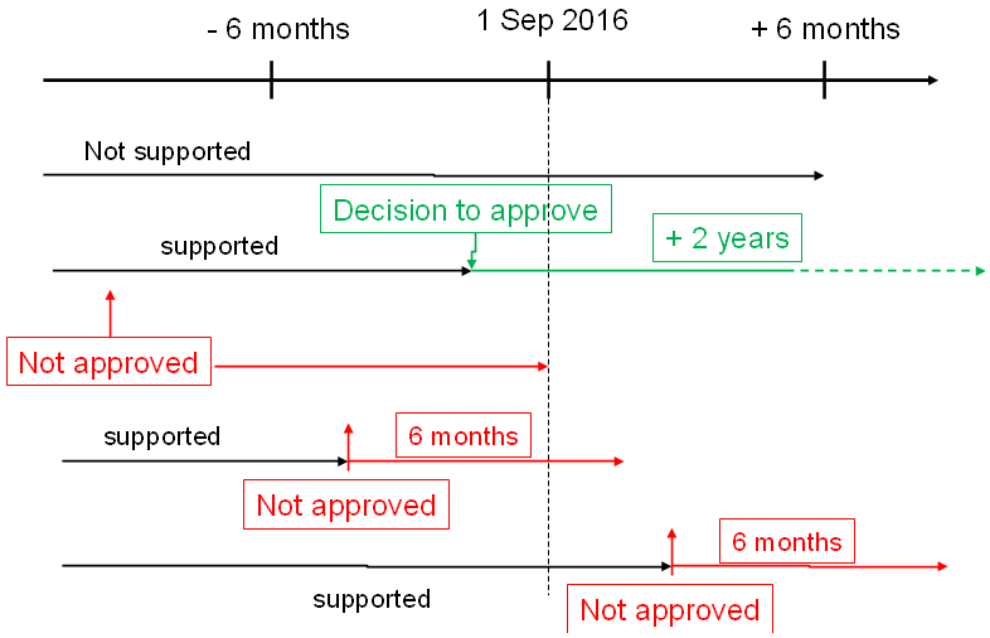
Deadlines for the placing on the market of treated articles (Art 94)

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.



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[7], i.e. 1 November 2016.

7 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.