FACT SHEET – EU BIOCIDAL PRODUCTS REGULATION (BPR)
February 2014 version N°2

(Supersedes any previous versions)

(Internal document aimed at providing information on current issues to FEICA members)

Executive summary

The EU Biocidal Product Directive (BPD) was revised and turned into an EU Regulation. This means that it will be directly applicable as such, in all EU Member States. The Biocidal Products Regulation (BPR) includes enhanced requirements for labeling, and in particular, for treated articles.

What is the issue / legislation?

The EU Biocidal Product Regulation requires:

- Each biocidal substance to be assessed at European level, and to be included in the Union list of approved active substances[1] to be used in one or several of the 22 biocidal Product Types (PT).
- Each biocidal product - containing substance(s) included in the Union list - has to be authorised at national level, i.e. in each Member state, or EU level for placing on the market.
- Each Biocidal Product (BP) has to be labelled according to health, environment and physical hazard – like chemical substances and biocidal functions.
- Treated Articles (TA) have to be labelled under certain conditions (see Q2)

Under the BPR, adhesives and sealants (A&S) containing biocides will be considered as 'treated articles' (see Article 58 of the BPR).

Question and Answers

Q1) Generally, A&S manufacturers use biocidal substances/products for the preservation of their own manufactured products (e.g. materials with "in-can preservation" or A&S protected against deterioration by microbial attack). Are these 'treated materials or articles (containing a biocidal product)' considered as 'biocidal products'?

A: **No**. Only those products having a primary **biocidal function** (i.e. action against unwanted organisms) are regarded as 'biocidal products'. By contrast, **the primary function (or intended purpose) of A&S is in most cases bonding and sealing respectively**, so they are not biocidal products but **TREATED ARTICLES,** and hence do not need an authorisation – see decision tree provided in Annex I.

Q2) When must Treated Articles be labelled according to article 58?

A: *The labelling information listed under Article 58(3) applies to Treated Articles IF:*

*-> **a specific claim** regarding the biocidal **properties** of these treated materials/articles is made by the manufacturer, **or***

*-> **required by** the conditions associated with **the approval of the active substance(s)** contained in the biocidal substance/product, that is incorporated or used in the 'A&S treated materials/articles'.*

***Q3)* What is a claim regarding a biocidal property?**

A: *In the context of Article 58(3) of the BPR, such a claim is a statement indicating or implying that the treated article has a certain degree of protection against unwanted organisms.*

(1) List of approved substances: http://echa.europa.eu/web/guest/regulations/biocidal-products-regulation/approval-of-active-substances/list-of-approved-active-substances

- ***Biocidal property*** *– in layman's term might also be considered as 'internal effect' or 'protect**ed**'*

*The 'biocidal property of a treated article', means a property resulting from the fact that the mixture or article has been **treated** with or **intentionally incorporates** a biocidal product with a view to protect its properties or function, or extend its durability or shelf-life.*

- ***Biocidal function*** *– in layman's term might also be considered as 'external effect' or 'protect**ing'***

A 'biocidal function' means the function 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.

Q4) A company imports from outside the EU a mixture containing a biocide (i.e. approved for PT 6 use, as "in-can preservative"). Does the company need a 'letter of access' for importing the TA? (i.e. adhesive with a preservative)? Does the company need to obtain an authorisation for the TA?

A: *The obligation of manufacturers or importers (M/I) of 'treated articles' is to make sure that the **active substance** contained in the biocidal substances/products with which they were treated is **approved for the required Product Type** (cf Q5), **and to ensure that all applicable labelling requirements are fulfilled (as appropriate! cf Q2).***

Q5) Which Product Types[2] (PT) are relevant for adhesives and sealants?

A: A&S typically use PT6 – "in-can preservatives", PT7 – "film preservatives", PT9 – "fibre, leather, rubber and polymerised materials preservatives", PT10 – "masonry preservatives".

*M/I of **'treated articles'** do not have to obtain authorisation for placing on the market their A&S – unless the treated article has a primary **biocidal function** (as it is then, a biocidal product). TA for which biocidal properties are claimed, need to report the information on the label – see Annex II. Upon request, the supplier of a TA must provide information on the biocidal treatment of such TA - free of charge, and in 45 days.*

How are FEICA member companies impacted?

- All biocidal substances put on the EU market in A&S, must have been approved in the EU.
- All biocidal products purchased in the EU for formulation of A&S, must have been authorized for making available in the EU. All biocidal substances imported into the EU as part of A&S, must have been authorized in the EU and included in the Union list.
- Confirmation of approval needs to be obtained from biocidal substance and/or biocidal product producers.

-> Companies that put on the market **formulated chemical products that are subject to CLP**, need to classify and label according to the CLP. We understand that this would cover the labelling requirements under the BPR, but some of the additional requirements stated on this last regulation **may** also apply (e.g. substance authorization number, indication of nanomaterials).

-> Companies that put on the market **treated articles that are not subject to EU CLP regulation, may have additional labelling requirements** laid down in **article 58** of the BPR. See Q/2

What is FEICA doing / how can FEICA help you?

Together with its member experts, FEICA was involved in the EU legislation revision process, by providing input during the public comment phases of the EU Co-decision process. It was achieved that imported products can contain approved active (biocidal) substances, rather than only authorised BP. FEICA also met the Commission's DG Environment, and provided comments during the discussions of the 'trilogue meetings', aiming to get a better regulation. FEICA will continue assisting its members with further publications (i.e. specific Q&A, etc.) in case these are needed.

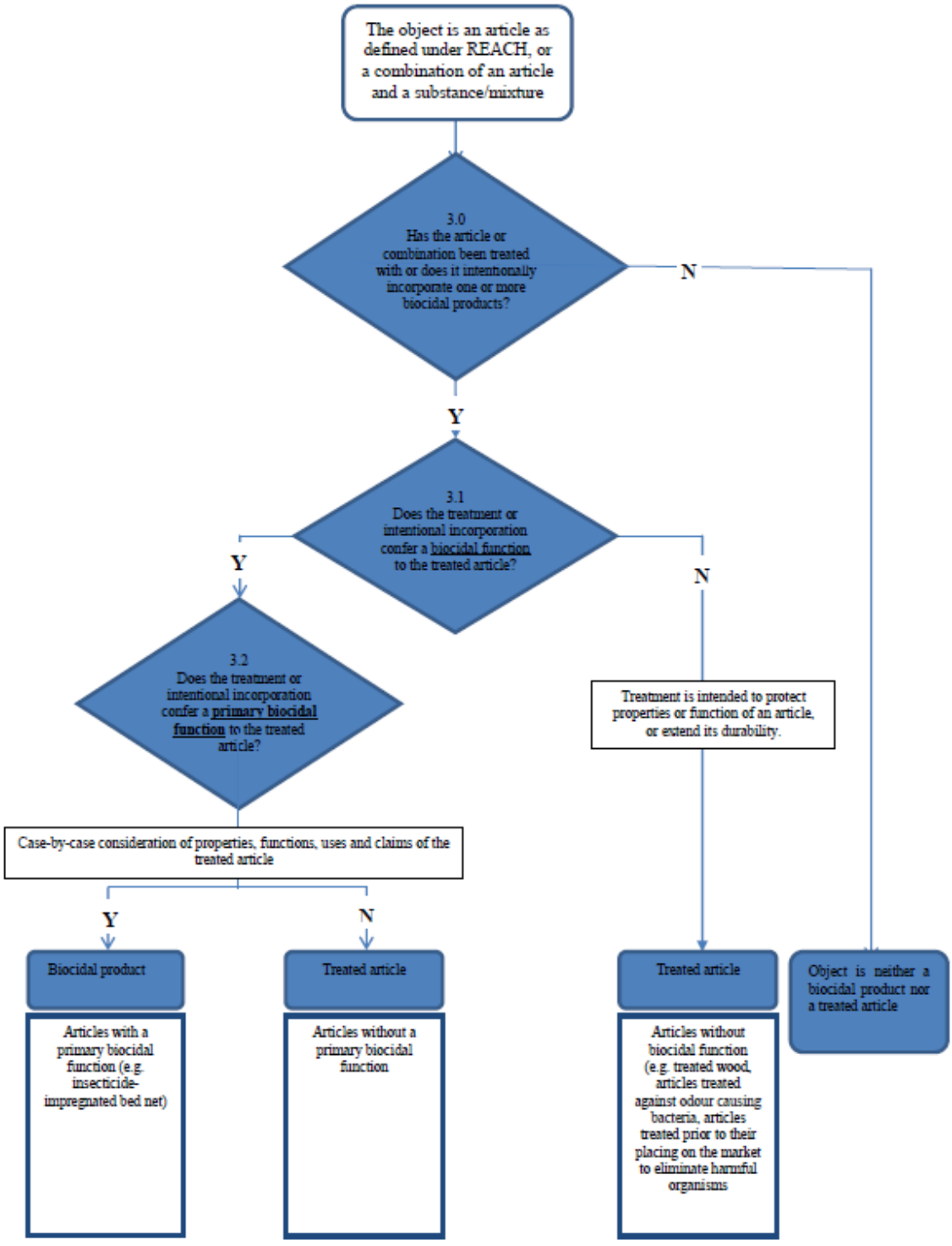
Next steps and potentially related upcoming events

The Biocidal Products Regulation applies since the **1st September 2013** - with transitional periods, for certain provisions (see annex II).

[2] Product Types: http://ec.europa.eu/environment/chemicals/biocides/biocidal-products/product-types_en.htm

ANNEX I

Decision tree to determine whether a product is a 'Biocidal Product' (BP) or 'Treated Article' (TA)



Source: EU Commission guidance on how to handle treated articles under the (BPR)
http://echa.europa.eu/web/guest/regulations/biocidal-products-regulation/treated-articles

ANNEX II

Labelling of Treated Articles (TA) and Transitional Provisions

Type of TA	TA **with primary biocidal function**	**TA WITH CLAIM on properties**	TA **without claim** (*)
Labelling requirements	*It is a **Biocidal product**. Labelling requirements as required by BPR*	*Example of a claim regarding the biocidal properties of TA: "contains a preservative against microbial deterioration" (see Guidance on TA for similar statements).* *Such a claim triggers the **labelling requirements specified in Art 58 (3) of BPR** - **unless equivalent provisions** are covered by other legislation (FEICA understands like CLP). In this case the biocidal substances **claimed** must be reported on the label, while the other non-claimed biocides neither have to be declared by BPR nor by CLP provided they are below the limits laid down in the latter.*	*In this case no labelling requirements under BPR apply, but as required by other legislation to protect human & animal health or the environment such as EU CLP Regulation – i.e. those A&S would be considered chemical products and must be classified and labelled in accordance to that Regulation. Thus, biocidal substances must be reported on the label of the treated article (i.e. adhesive or sealant) according to the concentration limits laid down in the CLP.*
Other requirements	*Product authorisation is required*	*No authorisation for placing on the market, but AS must be approved (or in review program!). **TA cannot be placed on the market after 1 September 2016 if the AS is not approved for the relevant PT and no dossier has been submitted before that date!** (see transitional provisions)*	*No authorisation for placing on the market, but AS must be approved (or in review program). See transitional provisions*

(*) NOTE: It should be noted that additional labelling requirements may be required for TA without biocidal claims, if during the assessment of the AS it is found that specific labelling provisions are necessary (see Q/2).

Transitional measures for treated articles

Treated articles can only be placed on the EU market when the Active Substance (AS) in that TA has been approved in EU for that application. However **for those AS not yet in the approval process there is a transition period,** so that they can continue to be present in TA placed on the market until a decision is made.

- **From 1 September 2013**, the **active substances** contained in the biocidal product with which the TA were treated or which they incorporate, have to be either **already approved or under evaluation** for the relevant product-type: if a non-approval decision is made for the AS used to treat the article, it should no longer be placed on the market as from 180 days from this decision.
- For **active substances** which are **not yet in the approval process, there is a transition period until 1 September 2016.** If an AS is not supported under this transitional measure, the treated article must be removed from the market by that date.

Hence, before placing a treated article on the EU market FEICA members should make sure that the AS is either approved or under review for the PT. To that aim it is recommended **to consult the status of the Active Substances** used to treat their articles.

Contacts for more info / support

FEICA Secretariat: Divina Gómez (d.gomez@feica.eu)

Chairman of the HazPro TWG: Axel Hessland (axel.hessland@klebstoffe.com)

The FEICA National Association Members: Until the completion of the AS review program (2024), ***individual BPs*** placed on the EU market should follow the existing National legislation of the relevant countries. For support on this National legislation, please refer to your specific National Association.

References

- Regulation (EC)No 1272/2008 on classification, labelling and packaging of substances and mixtures: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:en:PDF

- Regulation (EU)No 528/2012 concerning the making available on the market and use of biocidal products: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:167:0001:0123:EN:PDF

- **Guidance on treated articles:** http://echa.europa.eu/web/guest/regulations/biocidal-products-regulation/treated-articles

- Guidance on Information requirements concerning BPR: http://echa.europa.eu/documents/10162/15623299/biocides_guidance_information_requirements_en.pdf

Further information on Biocides:

- DG ENV website: http://ec.europa.eu/environment/biocides/index.htm
- ECHA: http://echa.europa.eu/en/contact/helpdesk-contact-form/enquiry-on-biocides
- JRC website: http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides

Further information on the CLP:

- Commission website: http://ec.europa.eu/enterprise/sectors/chemicals/documents/classification/
- ECHA website: http://echa.europa.eu/web/guest/regulations/clp

[i] *This document has been designed using the best knowledge currently available, and is to be relied upon at the user's own risk. The information is provided in good faith and no representations or warranties are made with regards to the accuracy or completeness, and no liability will be accepted for damages of any nature whatsoever resulting from the use or reliance on this paper. This document does not necessarily represent the views of all member companies of FEICA.*