Human Environment and Transport Inspectorate
Ministry of Infrastructure and the Environment

Information Leaflet

Supervision on Treated Articles

January 2014

The Human environment and Transport Inspectorate (ILT) and the Netherlands Food and Consumer Product Safety Authority (NVWA) are responsible for the supervision on the compliance of rules concerning the placing on the market of biocidal products and articles treated with biocidal products.

They work close together with other Dutch Inspectorates and Boards. They also work together with inspectorates within the EU, since new EU-legislation came into force on September 1, 2013. For the first time articles which are treated with biocide have to meet certain requirements. The active substance in the biocide needs to be approved by the EU or an application for approval must be submitted. There are also labelling requirements for treated articles.

1. European rules and a level playing field

Various European directives and regulations are in force in order to protect human health, animal health and the environment against toxic substances and to establish a level playing field on the European market. One of these regulations concerns the making available on the market and use of biocidal products. The placing on the market of articles treated with biocides is also regulated in the so called Biocidal Products Regulation, which came into force on September 1st, 2013 (Regulation 528/2012/EU).
This regulation dictates that biocides should only be made available or placed on the market after an evaluation of their risks and national or EU authorization. The user of biocidal products is also obliged to comply with the user instructions set out as authorization conditions. Articles that have been treated with a biocide do not need authorization.

However, subject to transitional measures, they can only be placed on the market (defined as first placed on the market) when the active (biocidal) substance(s) in that particular treated article has (have) been evaluated for that specific purpose. For both biocides and treated articles labelling requirements apply. The labelling obligation applies to treated articles from 1st September 2013. This note focuses on treated articles only.

What is a treated article?

The Biocidal Products Regulation (BPR) defines treated articles as follows:

Treated article: any substance, mixture or article which has been treated with or intentionally incorporates one or more biocidal products.

This definition contains a reference to 'biocide' or 'biocidal product':

Biocides: any substance or mixture which, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with 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.

It is crucial to understand that according to these definitions a substance or mixture can also be a treated article. Furthermore, it is also important to know that the definition of a biocidal product indicates that:

A treated article that has a primary biocidal function shall be considered a biocidal product.

Exceptions
There are two exceptions:

1 Articles that are biocidal products must comply with other BPR-obligations, and
2 Articles where the sole biocidal treatment was the fumigation or disinfection of premises or containers used for storage or transport and where no residues of the biocidal product are expected to remain from such a treatment.

Gebruiksaanwijzing en informatieplicht
The Regulation makes clear that where necessary to protect human health, animal health or the environment, a treated article should always be accompanied with instructions, including precautions. Furthermore, at a consumers request any supplier of a treated article has to provide information about the biocidal treatment of the treated article within 45 days.

Type of treated article There are three types of treated articles:	Active substance (AS) requirements	Labelling requirements
A. Treated article without any claim or reference regarding to biocidal properties (e.g. paint or ink containing in-can preservatives).	AS must be approved or in review program. If not, an application for approval must be submitted before 1 September 2016.	No labelling requirements (unless other legislation applies).
B. Treated article with claim regarding biocidal properties or claim arising from treatment with a biocidal product. (e.g. tent cloth incorporating an insect repellent).	As above.	Labelling is required as specified in art 58(3) BPR, unless equivalent provisions are required in other EU legislation.
C. Treated article with primary biocidal function (e.g. disinfecting detergent).	Article is a biocide and authorization is necessary before making available on the market.	Labelling is required as part of authorization (see also art 22. BPR) (No labelling requirements according to Art 58(3) BPR)

In case of a treated article without biocidal claim (A) the situation may arise that during the assessment of the active substance it is determined that specific labelling is necessary because of the active substance it was treated with or incorporates. Additional labelling requirements are then required.
In addition, the labelling obligations applicable to a treated article depend on the extent of the biocidal properties of the treated article as claimed on the label or in any promotional material (e.g. in advertisements or on the Internet). The regulation states that where biocidal properties are claimed information must be given on the label. When the promotion or claim is such that the biocidal function is primary the treated article is considered to be a biocide product (C) and an authorization for the biocidal product must be obtained before it can be placed on the market or used as a biocide.

4. Labelling requirements

Where a treated article has a biocidal claim or otherwise refers to the biocidal properties of the active substance with which it is treated (B and C), the person placing the product on the market for the first time has to provide certain information on the label of the treated article.
The required information is:

- A statement that the treated article incorporates biocidal products.
- The biocidal property of the treated article.
- the name of the active substance(s).
- If present, the name of each biocidal (nano-) substance followed by the word ' nano' in brackets.
- Any relevant instructions for use.

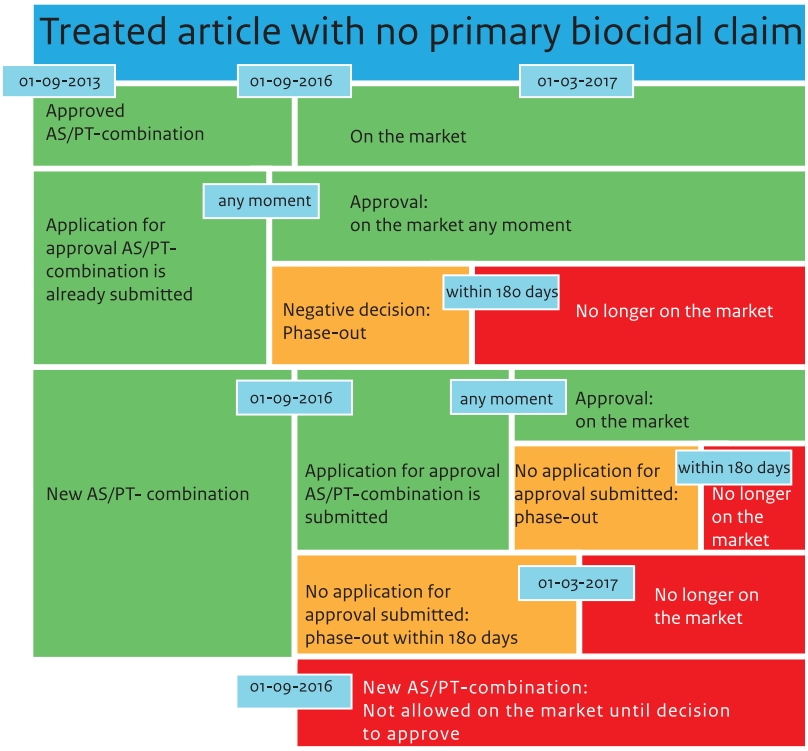
These labelling obligations do not apply where other EU requirements provide equivalent information.

5. Transitional provisions

The Biocidal Products Regulation came into force on September 1, 2013. For labelling obligations (as described above) no transitional arrangement applies. Treated articles have to comply with the labeling requirements from September 1, 2013. However, there are transitional measures for the active substance(s) in the biocidal products with which the article is treated. Three situations are possible:

1. The active substance(s) has (have) been assessed and approved for use in the product type of the treated article: the treated article can remain on the market (+ labeling requirements, see above)
2. The active substance(s) is (are) in the review program and a dossier(s) has (have) been submitted for approval but has (have) not yet been assessed for this application: the treated article can remain on the market until a decision is published; if the decision is negative: the article has a phase-out period of six months (+ labeling requirements, see above).
3. The active substance(s) is (are) not in the review program: the treated article can remain on the market provided a dossier for approval of the active substance is submitted before September 1, 2016. If no dossier is submitted by this date, the treated article must be removed from the market before February 28, 2017. When the assessment leads to a negative decision the treated article also has a phase-out period of 180 days from the date of this decision.

Treated articles can't be placed on the market after September 1, 2016 if the active substance is not approved for the relevant PT and no dossier has been submitted before this date. This is shown schematically in following figure:



More information

In the *Note for guidance on treated articles* the Commission and EU Member States set out detailed questions and answers on treated articles. This guidance document is available on the website of the European Chemicals Agency (www.echa.eu) together with an increasing amount of information on the requirements in BPR for biocides and treated articles.
More information is also available on www.biociden.nl.

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