AN INDUSTRY GUIDE FOR THE SUPPLY CHAINS OF THE NONWOVENS AND RELATED INDUSTRIES

Assisting EDANA and its Member Companies prepare for the Requirements under the EU Biocidal Products Regulation (BPR)

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Disclaimer:

This document intends to provide guidance to EDANA's members companies, in order for them to assess their obligations under the BPR. Whilst the content of this document has been drafted with the support of external legal and regulatory counsel, it is for informational purposes only and neither constitutes nor replaces specific legal advice or opinion.

TABLE OF CONTENTS

THE AIM OF THIS GUIDE

Regulation (EU) No. 528/2012 of the European Parliament and of the Council of 22nd May 2012 concerning the making available on the market and use of biocidal products ("the BPR") is the new European Union ("EU") legislation on biocidal products. The BPR was published in the Official Journal of the European Union on 27th June 2012[1], and its provisions applied as of 1 September 2013. It replaced and repealed Directive 98/8/EC concerning the placing on the market of biocidal products ("the BPD")[2]. The BPR has already been amended, most importantly by Regulation (EU) No. 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 ("the Amendment"); these most recent changes are already reflected in this Guide[3] and can be found in the consolidated version of the BPR published in the Official Journal of the European Union on 25 April 2014.

Several guidance documents have been published by the Commission to facilitate the interpretation of certain requirements of the BPR. These documents were also the subjects of further debates and revisions; such as the Note for Guidance on Treated Articles, which has been finalised and published in December 2014[4]. This Guide is based on the interpretation presented in the Note for Guidance. Please note that the Commission's Note for Guidance is not legally binding and that changes to the Note in relation to definitions and examples may be added over time.

Transitional measures have been put in place in the BPR to ensure smooth application of the new requirements to active substances and biocidal products previously regulated under the BPD, or to active substances and applications not subject to any requirements under the previous Biocidal Products regime. The articles laying down the transitional measures underwent some critical changes as a result of the Amendment. These are identified in the document.

EDANA is issuing this Guide in order to help its members and their suppliers to comply with the obligations they may have under the BPR. The focus of this document is on the new requirements for treated articles, as interpreted by the final Note for Guidance, however other elements of the BPR are also covered in brief.

This guidance document is addressed to all EDANA member companies and other stakeholders who place treated articles on the market in the EU, or participate at any point in their supply chain. Please see www.edana.org for an overview of the relevant EDANA sectors.

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[1] OJ L 167, 27.6.2012, p.1.

[2] OJ L 123, 24.4.1998, p.1.

[3] Commission Implementing Regulation (EU) No 88/2014 of 31 January 2014 specifying a procedure for the amendment of Annex I to the BPR; Commission Delegated Regulation (EU) No 837/2013 of 25 June 2013 amending Annex III to the BPR as regards the information requirements for authorisation of biocidal products; Commission Implementing Regulation (EU) No 564/2013 of 18 June 2013 on the fees and charges payable to the European Chemicals Agency pursuant to the BPR.

[4] http://echa.europa.eu/regulations/biocidal-products-regulation/treated-articles

DISCLAIMER

This Guide looks into the provisions of the BPR with a particular focus on treated articles. However, please note that some provisions are subject to interpretation and that the European Commission has stated that a case-by-case decision by the Commission will be the preferred approach to define whether a specific product is a treated article, a biocidal product or neither. The Commission may then issue implementing acts for these decisions in accordance with Article 3.3 of the BPR.

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INTRODUCTION TO THE BPR

THE BPR: SCOPE AND OBJECTIVES

The BPR aims to harmonise EU rules on the making available on the market and use of biocidal products, while ensuring a high level of protection of both human and animal health and the environment.

It does this by laying down rules for:

- Establishing a harmonised EU list of **approved active substances** that may be used in biocidal products
- **Authorisation** of biocidal products and making available on the EU market
- **Mutual recognition** of authorisations within the EU
- And placing on the market of **treated articles**.

The BPR applies to products **intentionally** marketed as "biocidal products" and the active substances they contain, consist of or generate. The Regulation also includes some exemptions in Article 2.2., as it does not apply to products falling under the scope of for example the Cosmetics Regulation and the Medical Device Directive.

The BPR has widened the scope of the BPD; it has in particular introduced rules for **"treated articles"** defined in Article 3.1 (l) as **"any substance, mixture or article which has been treated with or intentionally incorporates one or more biocidal products"**. Treated articles, which were not formally regulated by the BPD, are now for the first time explicitly regulated under the BPR.

The BPR keeps a two-step approach for the authorisation of biocidal products.

- All active substances which biocidal products are consisting of, containing or generating should be approved for the relevant application/product type before the associated biocidal products may be authorised.

- Biocidal products are subject to a prior authorisation procedure before placed on the market for a specific application in the Member States of the EU.

Importantly, in order to provide a level playing field, the BPR provides that as of 1 September 2015, biocidal products shall not be placed on the market unless either the active substance supplier or the biocidal product supplier is listed as such for the relevant product type(s) on a list managed by ECHA (the so called Article 95 list) [5].

As far as the nonwovens and related industries are concerned, the range of products placed on the market as biocidal products remains quite small under the BPR. However, the new rules on treated articles may potentially apply to few materials/products sold by EDANA members whose products were outside the scope of EU biocides legislation in the past.

For this reason, this guidance focuses primarily on the rules for treated articles. Where relevant, reference is made in the text to additional guidance on the rules for biocidal products.

[5] The list of active substances is available on http://echa.europa.eu/web/quest/information-on-chemicals/biocidal-active-substances and the list of active substances and suppliers on http://echa.europa.eu/information-on-chemicals/active-substance-suppliers

KEY TERMS IN THE BPR

Knowing the definitions of the following terms is essential to understand how the BPR affects your products.

- An **active substance** is a substance or a micro-organism that has an action on or against harmful organisms. Hence, the biocidal function of an active substance is an intrinsic property.

  Note:

  The BPR distinguishes between 2 categories of active substances:

  An existing active substance is a substance, which was on the market on 14 May 2000 as an active substance of a biocidal product and is participating in the Review Program of existing active substances in relevant product types.

  A new active substance is a substance, which was not (yet) on the market on 14 May 2000 as an active substance of a biocidal product.

  This categorisation does not apply to substances that are on the market as active substances of biocidal products solely for scientific or product and process-oriented research and development.

- A **micro-organism** is any *microbiological entity*, cellular or non-cellular, capable of *replication* or of transferring genetic material, including lower fungi, viruses, bacteria, yeasts, moulds, algae, protozoa and microscopic parasitic helminths.

- A **harmful organism** is an organism, including pathogenic agents, which has an unwanted presence or a *detrimental effect on humans*, their activities or the products they use or produce, on animals or the environment.

- A **biocidal product** is:

  Any substance or mixture, 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.

  Any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used 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.

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

- A **primary biocidal function** is not defined in the legal text but is addressed in the Note for Guidance on treated articles from the European Commission[6] as "a biocidal function of first rank, importance, or value compared to other functions of the treated article".

The Commission Guidance defines the "function" of a treated article as the "intended purpose" for which the treated article is supplied. A treated article with a "biocidal function", by analogy, is a treated article whose intended primary function is to destroy, deter, render harmless, prevent the action of or otherwise exert a controlling effect on any harmless organism by means other than mere physical or mechanical action. The Commission Guidance also states that a treated article has more than one function if it serves more than one intended purpose.

[6] CA Sept13- Doc.5.1.e (Revision 1, December 2014)

Determining whether the biocidal function of a treated article is its **primary function**, however, is complex. A treated article whose exclusive function (resulting from the treatment with or intentional incorporation of biocidal products) is to control harmful organisms has a primary biocidal function. However, in cases where a treated article has multiple functions, at least one of which is biocidal, the following elements are currently proposed as criteria for determining whether the biocidal function is primary:

1. Intended use and purpose of the treated article

2. Prominence of claims made: If a claim refers to the biocidal function and is given greater prominence than other claims, the biocidal function could be considered primary

3. Whether a public health claim is made

4. Concentration of the active substance(s) in the treated article is important, whether it is comparable to an existing biocidal product

5. Mode of action of the active substance(s) or the treated article (in particular whether it would be identical to that of an existing biocidal product)

6. The target species (in particular when that species is not harmful to the treated article itself)

The relevance of the above determination is that treated articles with a primary biocidal function are regulated as biocidal products and must meet all associated requirements. However, a treated article with no primary biocidal function is still subject to the provisions of the BPR, as described in details in Chapter 2 of this Guidance.

- Making available on the market means any supply of a biocidal product or of a treated article for distribution or use in the course of a commercial activity, whether in return for payment or free of charge

- Placing on the market means the first making available on the market of a biocidal product or of a treated article

- A treated article is any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products

The terms "substance", "mixture" and "article" are not defined in the BPR, however the definition of these terms as given in the REACH Regulation 1907/2006 apply[7].

[7] BPR Article 3(2). These definitions are in REACH Article 3(1-3).

Note:

Readers familiar with REACH will recall that various types of substances – including polymers, cellulose pulp and non-dangerous, non-chemically modified natural substances – are exempt from REACH's substance registration obligations. However, these exemptions are specific to REACH and their existence does not mean that such substances fall outside the scope of the BPR.

BIOCIDAL PRODUCTS AUTHORISATION, A 2-STEP PROCESS:

APPROVAL (AND RENEWAL) OF ACTIVE SUBSTANCES

The provisions of the BPR concerning approval of active substances are contained in Chapter II (Articles 4-11) while the renewal of their approval is dealt with in Chapter III (Articles 12 16). The approval of an active substance is for an initial period of maximum 10 years, which can be renewed.

The active substance supplier must put together an active substance dossier with the data listed in Annex II to the BPR, as well as a dossier for requesting at least one biocidal product authorisation representative of the active substance used in the relevant product type.

The dossier has to be sent to ECHA, which allocates it to an agreed national competent authority, with fees having to be paid to both the Agency and the authority. The national competent authority reviews and evaluates the dossier. ECHA will submit its opinion on the evaluating authority's conclusions to the Commission. The latter will adopt an implementing decision approving, or not, the active substance. A list of all approved substances is made available to the public[8].

In accordance with Article 28 of the BPR, an approved active substance may be included in Annex I to the BPR[9] by a Commission delegated act provided it does not give rise to concerns.

At least 550 days before the end of the approved period, the applicant has to submit a renewal dossier including all relevant data generated since the approval together with an assessment of whether the active substance still qualifies to be approved under the conditions laid down in the BPR. Fees have to be paid to the Agency and the evaluating competent authority. The Commission adopts an implementing decision.

The Commission may review the approval of an active substance at any point where there are indications that the conditions laid down in the Regulation are no longer met, or if there are indications that the use of treated articles or biocidal products raises concerns for human health or the environment.

[8] See substances on http://echa.europa.eu/en/regulations/biocidal-products-regulation/approval-of-active-substances/list-of-approved-active-substances and suppliers on http://echa.europa.eu/information-on-chemicals/active-substance-suppliers

[9] See Commission Implementing Regulation (EU) No 88/2014 of 31 January 2014 specifying a procedure for the amendment of Annex I to the BPR

SUBSTITUTION

Active substances, which meet the definition of candidates for substitution are subject to a different regime under the BPR.

They will not be approved for more than seven years, even in the case of renewal. If the active substance meets one or more exclusion criteria, it will only be approved for five years.

When an active substance is identified as a candidate for substitution, products containing that active substance will have to be subject to a comparative assessment at the time of authorisation and will only be authorised if there are no better alternatives.

An active substance will be defined as a candidate for substitution if:

- It meets at least one of the exclusion criteria[10]
- It is classified as a respiratory sensitizer
- Its toxicological reference values are significantly lower than those of the majority of approved active substances for the same product-type and use
- It meets two of the criteria to be considered as PBT
- It causes concerns for human or animal health and for the environment even with very restrictive risk management measures
- Or it contains a significant proportion of non-active isomers or impurities.

AUTHORISATION OF BIOCIDAL PRODUCTS

The BPR rules that biocidal products shall not be made available on the market or used unless authorised in accordance with the provisions of the Regulation. These provisions on authorisation of biocidal products are contained in Chapter IV -IX of the BPR.

A new provision of the BPR is that besides the traditional national authorisation granted in a given Member State and opening the possibility for mutual recognition, the BPR also provides for a Union authorisation.

[10] Some active substances are excluded from the approval procedure, notably if they meet the criteria to be classified as CMR (Carcinogenic, Mutagenic or toxic to Reproduction) 1A or 1B, PBT (Persistent, Bioaccumulative and Toxic) or vPvB (very Persistent and very Bioaccumulative), or have endocrine disrupting properties.

Further, the BPR elaborated on the so-called **"simplified authorisation procedure"** (Article 25) for biocidal products which meet the following cumulative conditions:

- **All the active substances appear in Annex I of the BPR** and satisfy the conditions laid out in that Annex
- The biocidal product does not contain any substance of concern
- The biocidal product does not contain any nanomaterial
- The biocidal product is sufficiently effective
- And the handling of the biocidal product and its intended use do not require personal protective equipment.

The simplified authorisation procedures provides much shorter timeline for the biocidal products to be authorised once a dossier is submitted, due to the sole intervention of the national competent authority in the authorisation process, as well as suppressing the need for mutual recognition for placing such biocidal products on the EU market.

Note:

Although the above provisions represent several changes compared to the regime established under the BPD, it is expected that the range of biocidal products manufactured by EDANA members will continue to be limited. The main nonwoven products falling in this category are likely to be biocidal wet wipes, such as surface cleaning wipes that are marketed as having biocidal cleaning properties.

TRANSITIONAL MEASURES FOR ACTIVE SUBSTANCES AND BIOCIDAL PRODUCTS

ACTIVE SUBSTANCES

Article 86 of the BPR provides that active substances included in Annex I of Directive 98/8, i.e. approved under the previous regime, are deemed to be approved under the BPR and will be included on the so called Article 95 list of approved active substances for the relevant product types.

The BPR also provides for the continuation of the review programme of active substances started under the BPD. Biocidal products may contain active substances, which are being evaluated as part of the review programme. Article 89 indicates the time given to a biocidal product containing such active substances to achieve compliance with the BPR provisions once a decision concerning the active substance approval or non-approval was taken. The biocidal product will then need to be authorised, its existing authorisation modified or cancelled depending on the outcome of the active substance approval.

Article 90 provides transitional measures for active substances that have not been evaluated at the date of application of the BPR, on 1 September 2013. These active substances will be reviewed in accordance with the rules of the BPR, on the basis of the documents submitted in accordance with the BPD, with a possibility to submit additional information if required.

Where an active substance is contained in a biocidal product which was used to treat, or was intentionally incorporated in a treated article, the transitional measures provided in article 94 should be considered.

BIOCIDAL PRODUCTS

Article 91 provides that where an application for authorisation of a biocidal product was made before 1 September 2013 and the evaluation was not completed before that date, the authorisation will still be evaluated in accordance with the BPD.

However, where the biocidal product meets an exclusion or substitution criteria, the evaluation should be conducted in accordance with the provisions of the BPR.

Biocidal products, which had been authorised prior to 1 September 2013 may continue to be made available on the market until the expiry date of their authorisation.

Based on the transitional measures in Article 93, biocidal products outside the scope of the BPD which are, however, subject to the BPR may continue to be made available on the market if they only consist of, contain or generate active substances that were available on the market or used in biocidal products on 1 September 2013.

If for the active substances concerned no approval is seeked before 1 September 2016 or if approval is refused, the associated biocidal products will have to be phased out of the market.

TREATED ARTICLES

The most important provisions of the BPR for the majority of EDANA's member companies are those contained in Chapter XIII / Article 58 on the Placing on the Market of Treated Articles.

Under Article 58(2) of the BPR, a treated article may only be placed on the market when all active substances contained in the biocidal products which it was treated with or incorporates are approved for the relevant product types in accordance with the BPR.

TREATED ARTICLES: SCOPE OF THE BPR

Treated articles are defined in Article 3 (1) (l) of the BPR as "any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products".

Article 3(1,a) laying down the definition of biocidal product further clarifies that "a treated article that has a **primary biocidal function** shall be considered a biocidal product".

If the product has a primary biocidal function, the provisions of the BPR applicable to biocidal products will apply. In all other cases, the product will be regulated under the provisions applicable to treated articles.

REQUIREMENTS FOR TREATED ARTICLES

APPROVED ACTIVE SUBSTANCES

As mentioned previously, all active substances contained in the biocidal products that a treated article was treated with or incorporates must be approved in accordance with the provisions of the BPR and thus listed for the relevant product-type in the Union list of approved active substances or in Annex I.

The specific transitional measures provided under Article 94 which are applicable to active substances contained in biocidal products that a treated article was treated with or incorporates will have to be taken into account (see below).

Treated articles may be treated with or incorporate any biocidal products which consist of active substances that:

- In accordance with the transitional measures provided in Article 89, are under the review programme
- Are listed in Annex I to the BPR
- Or are on the approved active substances list

LABELLING AND CONSUMER INFORMATION REQUIREMENTS

Other than the approval of active substances, Article 58 provides for the requirements a treated article need to comply with before it can be placed on the market.

Article 58(3) provides for the labelling of treated articles required if:

- A claim is made by the manufacturer regarding the biocidal properties of the article
- Or the conditions of approval of one active substance it requires.

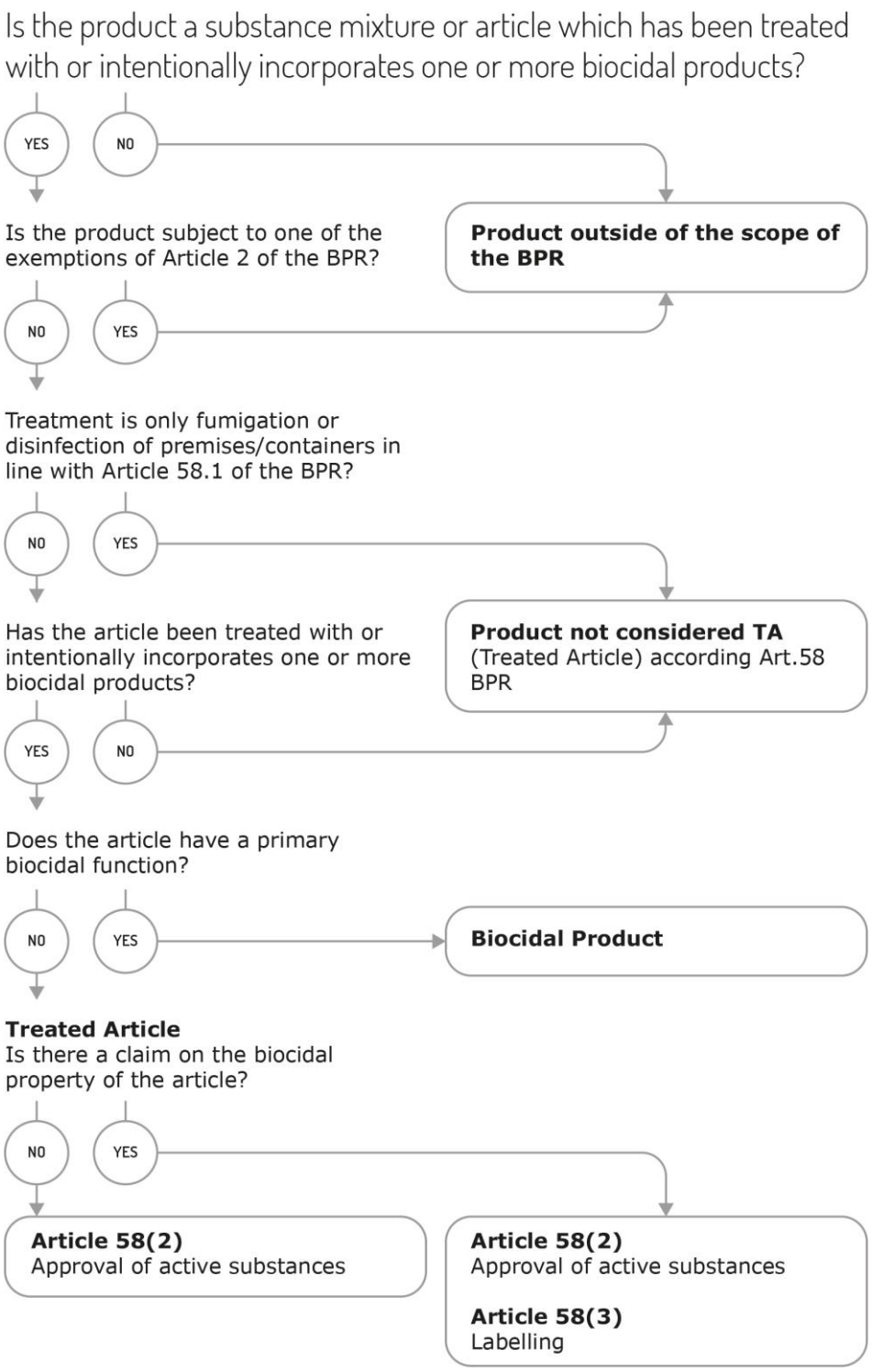
A compliant label must bear the following information:

- A statement that the treated article incorporates biocidal products
- The biocidal property attributed to the treated article where a claim is made
- The name of all actives substances contained in the biocidal products
- The name of all nanomaterials contained (indicating they are 'nano')
- And any relevant instruction for use

Article 58(4) provides an additional labelling requirement for all treated articles (not subject to the limitation of Article 58(3)) in the form of any relevant instructions for use and precautions to be taken if necessary for the protection of animal and human health and the environment.

Finally, Article 58(5) provides that the supplier of a treated article must provide information on the biocidal treatment of a treated article within 45 days of a request from a consumer.

DECISION TREE FOR SIMPLIFIED CASES



TRANSITIONAL MEASURES FOR TREATED ARTICLES

Article 94 of the BPR provides transitional measures for treated articles

By way of derogation from the provisions of Article 58(2) which requires that a treated article shall not be placed on the market unless all active substances contained in the biocidal products that it was treated with or incorporates are authorized for the intended use, a treated article containing only active substances which are under review for the relevant product type or for which an application for approval has been submitted before 1 September 2016 may be placed on the market according to the respective transitional deadlines.

For active substances, which are not yet in the approval process, a complete application dossier need to be submitted on the active substance by 1 September 2016. The active substance dossier must include data on the biocidal product in the relevant product-type.

If the active substance is not approved for the relevant product-type, articles which were treated with or incorporated a biocidal product containing this active substance should no longer be placed on the market as from 180 days from the decision of non-approval of the active substance.

In case no active substance dossier is submitted before 1 September 2016 and the active substance is not otherwise approved for the relevant product-type or use, the treated article may only be placed on the market until 1 September 2017.

COMMISSION GUIDANCE DOCUMENT AND DISCUSSION NOTES ON TREATED ARTICLES

CLARIFICATION OF ARTICLE 58 OF THE BPR AND NOTE FOR GUIDANCE WITH RESPECT TO COMPLEX TREATED ARTICLES

Article 58(2) does not distinguish between a treated article (which is the only term used in the BPR text) and components thereof. The final Note for Guidance clarifies that Article 58 of the BPR applies to treated articles (simple or "complex" (made up of a series of components) in the form in which they are placed on the market (i.e. as "finished goods"). It asserts that based on the definition of a treated article, the 'treating with' and 'intentionally incorporating' of a biocidal product should be made with the intention of conferring a biocidal property or biocidal function to the treated article for a beneficial and desired effect in the finished good.

EDANA welcomes the above interpretation of the Commission. It entails that products which are treated with or incorporate biocidal products in the course of their manufacturing for a specific biocidal function only at a given stage of the manufacturing process, but without an intended biocidal function or biocidal property in the finished good, as placed on the EU market are excluded from the scope of treated articles.

Following further discussions with stakeholders, the Commission included a Note for Discussion on treated articles as Appendix 3 to the Note for Guidance. This Appendix provides specific examples that help to define the conditions under which an article should be considered a "treated article" falling under the definition of the BPR.

Specifically, to define whether the potential presence of a biocidal active substance in a finished good is intentional, EDANA suggests member companies to use the indicators provided in this Appendix identifying whether the finished good might be considered a treated article:

These recommended indicators are:

1. Claims about the finished good or parts thereof
    a. About biocidal function and/or property
    b. Also covering implicit claims
2. Product type (list is available here)
3. The concentration of the active substance in the final article

For EDANA member companies, possible claims may relate to odour-controlling or disinfecting properties of a finished good. The classification of such a product as a treated article will always depend on the intended effect in the finished good and (even indirect) claims.

Member companies should also be aware of the product type(s) of the active substances used in the finished good and ensure that they can get this information from their suppliers. Depending on the product type, the classification can take place, as the Note for Guidance outlines likely classifications for individual product types. Please note that some product types can trigger a classification as treated articles, biocidal products or neither of these. In line with the Commission Guidance, EDANA therefore reminds its member companies that in case of conflicting views, a case-by-case decision made by the Commission upon the request of a Member State in accordance with Article 3.3 of the BPR is the decisive, harmonized position in the form of an implementing act, which is binding in all Member States.

APPENDIX

CASE STUDIES – WHICH OBLIGATIONS FOR WHICH PRODUCT?

The below case studies are indicative and based on BPR text and the examples mentioned in Appendix 1 of the Commission's Note for Guidance. As an introduction to the case studies from EDANA's supply chain, we have incorporated two examples from the Note's Appendix.

FINISHED GOOD	BIOCIDAL PRODUCT	TREATED ARTICLE	NEITHER A TREATED ARTICLE NOR A BIOCIDAL PRODUCT
Mixture		Mixtures like paints, glues, inks, detergents, etc. containing an in-can preservative	Complex articles containing e.g. glues, inks, paints which had in-can preservatives added in order to protect them during storage, where these preservatives have no further function in the finished good[11]
Paper			Paper made of paper pulp (cellulose) incorporating a preservative in order to protect the pulp (an aqueous mixture) during storage before use in the manufacturing of paper; equally incorporation of a preservative in other intermediates such as starch, pigments, coatings or fillers during storage[12]

[11] See Appendix 1 of https://circabc.europa.eu/sd/a/d7363efd-d8fb-43e6-8036-5bcc5e87bf22/CA-Sept13-Doc%205.1.e%20(Rev1)%20-%20treated%20articles%20guidance.doc

[12] See Appendix 1 of https://circabc.europa.eu/sd/a/d7363efd-d8fb-43e6-8036-5bcc5e87bf22/CA-Sept13-Doc%205.1.e%20(Rev1)%20-%20treated%20articles%20guidance.doc

FINISHED GOOD	BIOCIDAL PRODUCT	TREATED ARTICLE	NEITHER A TREATED ARTICLE NOR A BIOCIDAL PRODUCT
Surface disinfecting wipe	A wet wipe for surface disinfecting purposes, which carries a claim about killing bacteria on the package. The wipe will be considered a biocidal product, as the biocidal function of the wipe will likely be primary in line with Article 3.1 (a) of the BPR. Such a wipe has to be registered under product type 2 (disinfectant) and/or product type 4 (food and feed area disinfectants).		
Wipe for household purposes		A wipe for household purposes, e.g. a surface cleaning wipe, which contains an impregnating lotion that is preserved should be considered a treated article. The biocidal property of the preservative is intentional in the finished wipe; We can also conclude that: 1) the active substance in the wipe belongs to product type 6 (preservatives for products during storage) and 2) the preservative also has a biocidal function beyond storage, i.e. in the finished product; and 3) the concentration of the active substance is set at a level at which it will have an intentional biocidal function in the finished good.	

FINISHED GOOD	BIOCIDAL PRODUCT	TREATED ARTICLE	NEITHER A TREATED ARTICLE NOR A BIOCIDAL PRODUCT
Wipe for use on skin	A wet wipe for skin disinfecting purposes, which promotes a primary biocidal function. The wipe will be considered a biocidal product in line with Article 3.1 (a) of the BPR. Such a wipe has to be registered under product type 1 (human hygiene).		A wet wipe for use on skin (e.g. facial cleaning purpose) is considered a cosmetic product. According to Article 2 (j), the BPR does not apply to biocidal products or treated articles falling under the scope of the Cosmetics Regulation 1223/2009.
A nonwoven manufactured with processing water with biocides			During the manufacturing process, a biocidal product is added to the processing water to protect the product in this step of the manufacturing process without any intended biocidal effect in the finished good.
A nonwoven bound with a polymer dispersion and/ or binder containing in-can preservatives (with a biocidal function during storage).			The in-can preservatives (product type 6 preservatives for products during storage) have been added to protect the dispersion and/ or binder during storage and have no intended biocidal function in the finished good (the nonwoven).

FINISHED GOOD	BIOCIDAL PRODUCT	TREATED ARTICLE	NEITHER A TREATED ARTICLE NOR A BIOCIDAL PRODUCT
A nonwoven with biocidal treatment		The nonwoven manufacturer treats a nonwoven with a biocide in product type 9 (fibre, leather, rubber and polymerised materials preservatives) to obtain an intentional biocidal effect in the finished good. The finished nonwoven should be considered a treated article, as it has incorporated a biocidal product to obtain a biocidal property in the finished good. This biocidal property is not the primary function of the nonwoven.	
A nonwoven with a primary biocidal function	A biocide falling into product type 2 (Disinfectants and algaecides not intended for direct application to humans or animals) is added to a nonwoven to give an intentional antimicrobial function in the finished good. The nonwoven has no other intended purpose than to be used as an antiseptic wipe.		
A panty liner incorporating odour-masking or odour-absorbing technologies			A panty liner is manufactured with odour-masking or -absorbing technologies which is not based on antimicrobial action, but addition of perfume into the product. Its packaging carries a claim relating to odour, such as pleasant scent, no mal-odours etc. As the technology applied does not rely on a biocidal function, the panty liner (the finished good) will neither be considered a biocidal product nor a treated article.

FINISHED GOOD	BIOCIDAL PRODUCT	TREATED ARTICLE	NEITHER A TREATED ARTICLE NOR A BIOCIDAL PRODUCT
A nonwoven with odour-controlling technologies		A nonwoven is incorporated into a sole for use in footwear. The nonwoven has been treated with a biocidal product to give odour-controlling properties in the sole based on antimicrobial action. These properties will have an intended function in the finished good and the packaging of the sole contains a claim about reduction of bad smells. Both the nonwoven and the sole will therefore be considered as treated articles.	
A nonwoven incorporating a bleached fibre			The substance used for bleaching a fibre in the nonwoven does not confer an intended biocidal function to the finished good and the bleaching is not a biocidal 'treatment'. The substance used for bleaching is therefore not an active substance as defined in Article 3.1.c of the BPR.