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

EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
Directorate A – Green Economy
ENV.A.3 - Chemicals

NOTE FOR GUIDANCE

This document is an attempt to provide guidance in the interest of consistency, and has been drafted by the Commission services responsible for biocidal products with the aim of finding an agreement with all or a majority of the Member States' Competent Authorities for biocidal products. Please note, however, that Member States are not legally obliged to follow the approach set out in this document, since only the Court of Justice of the European Union can give authoritative interpretations on the contents of Union law.

Subject: Frequently asked questions on treated articles

The purpose of this document is to provide guidance on the implementation of the second subparagraph of point (a) of Article 3(1), Article 58 and Article 94 of Regulation (EU) No 528/2012 ('BPR').

It is structured in the form of questions and answers, addressing the most frequent issues raised in requests to the Commission.

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DEFINITIONS

Treated article

1. Question:

   What is a treated article?

   Answer:

   According to article 3(1)(l) of the BPR, a treated article is any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products.

Treating with vs. intentionally incorporating

2. Question: Is 'treating with' to be understood differently from 'intentionally incorporating'?

   Answer: 'Treating with' indicates that a biocidal product has been applied to a substance, mixture or an article.

   Intentionally incorporating' indicates that the biocidal product has been utilised in such a way (typically during the manufacturing of the treated article) that it becomes part of a mixture or article.

   However, in practice the distinction is of little significance for the application of Article 58 as in both cases only approved active substances can be used and the labelling requirements have to be complied with when a claim regarding the biocidal properties of the treated article is made, or when the conditions for the approval of the active substance(s) so require.

Biocidal product

3. Question:

   What is a biocidal product?

   Answer:

   According to article 3(1)(a) of the BPR, 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.

Active substance

4. Question:

What is an active substance?

Answer:

According to Articles 3(1)(c) and (g) of the BPR, an active substance is a substance or a micro-organism that has an action on or against harmful organisms. i.e. organisms, including pathogenic agents, which have an unwanted presence or a detrimental effect on humans, their activities or the products they use or produce, on animals or the environment.

Existing active substance

5. Question:

What is an existing active substance?

Answer:

An existing active substance is an active substance which was already available on the market in biocidal products on 14 May 2000 and which is under evaluation in the review programme for existing active substances used in biocidal products[1]. An active substance is regarded as 'existing' only for the product-type(s) for which it is being evaluated in the review programme.

New active substance

6. Question:

What is a new active substance?

Answer:

A new active substance is an active substance which is not regarded as 'existing' according to the above definition, i.e. an active substance which was made available on the market in biocidal products only after 14 May 2000 or which was not included in the review programme for evaluation. An active substance is considered 'existing' only for the product-types for which it is being evaluated in the review programme, but will be regarded as new for the product-types which are not included in the review programme.

[1] As established by Article 89(1) of the BPR.

PRINCIPLES

Biocidal property

7. Question:

What is meant by the ‘biocidal property of a treated article’?

Answer:

A biocidal property means a characterising quality or trait resulting from the fact that the mixture or article has been treated with or intentionally incorporates a biocidal product with the intention to prevent the action of harmful organisms. The term 'biocidal property' covers both biocidal actions on the treated article itself, and actions giving a biocidal function (see below) to the treated article.

Thus a treated article with biocidal function always has a biocidal property. Conversely, a treated article *without* biocidal function can nevertheless have a biocidal property, e.g. protection from microbial decay and thus increased durability of the article itself.

Antimicrobial treatments made, as examples, to:

- Prevent deterioration of plasticised PVC.
- Extend the lifespan of façade paints.
- Prevent odour.

would thus be expected to confer a biocidal property to the treated article.

Biocidal function of a treated article

8. Question:

What is a treated article with a biocidal function?

Answer:

The function of a treated article is the intended purpose for which the article is supplied and which it fulfils by one or more means. A treated article can have more than one function if it serves more than one purpose.

A biocidal function, by analogy with the definition of a biocidal product, 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.

A treated article with a biocidal function thus is an article which has amongst its intended purposes at least one that aims at 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. This function is not intended to protect the article itself or its original function, but to introduce an additional function which is biocidal. One could for instance expect a biocidal function to be conferred to a treated article when biocidal products belonging in

particular to the following product-types would be intentionally incorporated into a mixture or article.

PT2:	Disinfectants and algaecides not intended for direct application to humans or animals.
PT4:	Food and feed area disinfectants
PT18:	Insecticides, acaricides and products to control other arthropods.
PT19:	Repellents and attractants.

When a disinfectant is incorporated into textiles, tissues, masks, paints or any other article or material with the objective of producing a treated article which has the intended purpose to disinfect the disinfectant does not act as a preservative of the treated article but confers a biocidal function to the treated article.

Antimicrobial treatments made, as examples, to:

- Computer keyboard to prevent bacterial growth on the surface
- Hospital bedside cabinet to kill germs on contact
- Door handles to prevent cross-infection

would thus confer a biocidal function to the treated article.

In the case of product-types 18 and 19, the insecticide or repellent could either be added to protect the treated article itself, or to confer a biocidal function to the treated article.

9. Question:

How might one determine whether a treated article has a biocidal function?

Answer:

First of all, the article as such has to be supplied with the intended purpose of controlling harmful organisms. Secondly, at least one of the active substances in the biocidal product(s) intentionally incorporated in the treated article has to contribute to that purpose.

Some treated articles have an exclusively biocidal function, since an active substance contributes to the only intended purpose of the article. Such treated articles would by default be biocidal products.

Other treated articles have no biocidal function, even if their purpose is to control harmful organisms. In these cases, the active substance(s) in the treated article do(es) not contribute to that control, which is hence merely physical or mechanical. Examples include a wooden rat trap treated with a wood preservative, or a textile mosquito net treated with a textile preservative. According to BPR, such products would be considered treated articles, but not biocidal products.

A third category of treated articles have two or more functions, one of which is biocidal. Examples include clothes intentionally incorporating an insect repellent.

Such clothes have two intended purposes: To keep the body covered and warm and to have an action against insects. Whether a product having biocidal and non-biocidal functions is a biocidal product or a treated article depends on whether the biocidal function is primary (see below).

Primary biocidal function

10. Question:

What is a 'treated article with a primary biocidal function'?

Answer:

The term 'primary biocidal function' is used only in article 3(1)(a) of the BPR, and is not further defined in this regulation. In the given context a primary biocidal function can be interpreted as a biocidal function of first rank, importance, or value compared to other functions of the treated article. A 'treated article with a primary biocidal function' is thus a treated article that has one or more functions, of which one is a biocidal function that is of first rank, importance, or value compared to the other functions of the treated article.

11. Question:

Are there any criteria to determine whether the biocidal function of a treated article is 'primary', i.e. of first rank, importance, or value compared to the other functions of that treated article?

Answer:

Whether a biocidal function of a treated article is a primary biocidal function will need to be decided on a case-by-case basis, taking into account all individual properties and functions of the treated article, as well as its intended use.

A treated article which only has one function, and when this function is biocidal, has by default a primary biocidal function.

Examples include mosquito nets intended solely to control mosquitos, which are treated with insecticides or insect repellents. Such treated articles have only one intended purpose, and that purpose is not achieved by *mere* physical or mechanical action, although a physical or mechanical action (e.g. physical prevention of mosquitos from approaching humans) does also contribute to that intended purpose.

For treated articles which have more than one function, there are different criteria which could indicate that the treated article has a primary biocidal function.

Criteria to be taken into account for a decision could include, but are not limited to, the following:

- the intended use and purpose of the treated article,
- claims made regarding the function of the treated article, in particular when it would be identical to that of an existing biocidal product,

- the target species, in particular when the species would not be harmful to the treated article itself.

- the concentration of the active substance in the treated article, in particular when it would be comparable to that in an existing biocidal product,

- the mode of action of the active substance or treated article, in particular when it would be identical to that of an existing biocidal product,

According to Article 3(3) of the BPR, Member States may request the Commission to decide, by means of implementing acts, whether a specific product or group of products is a biocidal product or a treated article or neither.

12. Question:

What is the influence of a claim when determining a possible primary biocidal function of a treated article?

Answer:

The influence of a claim on the decision whether a treated article has a primary biocidal function will depend on the wording and presentation of the claim. The following aspects may be considered in particular:

- the prominence of the claim

If a claim regarding a biocidal function of a treated article is given greater prominence than other described properties or functions of that treated article, that function may be regarded as a primary biocidal function and hence the treated article may be considered as a biocidal product.

- whether the claim has public health relevance

It is important to note that the objective of BPR is not only to protect human health and the environment from harmful effects of biocidal products and treated articles as such, but also from products or articles with biocidal function that might have a detrimental effect on public health due to insufficient efficacy. If a claim is made which has public health relevance (i.e. regarding an action against one or more pathogenic organisms, see also question 34) it is particularly important that a treated article does have the effect which users would be entitled to expect in view of the claim made[2]. In such cases, the biocidal function may be considered to take higher rank than other, non-biocidal functions and it needs to be considered whether the treated article may be a biocidal product subject to authorisation[3] before placing on the market.

[2] For an analogy with medicinal products, see Case *227/82 Van Bennekom [1983] ECR 3883* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:61982CJ0227:EN:PDF

[3] The UK disagrees, based on the text of BPR, that the presence of public health claims is a relevant factor in determining whether a treated article has a primary biocidal function, and hence is a biocidal product. Therefore the UK disagrees with this paragraph of the guidance document.

The assessment of whether a treated article with a claim of public health relevance has a primary biocidal function must be made on a case-by-case basis, taking into account also the criteria given in question 11.

13. Question:

What rules govern a treated substance or mixture with a biocidal function? Is it relevant whether the biocidal function is primary or not?

Answer:

If a substance or mixture, in the form in which it is supplied to the user, has an intentional biocidal function and is not subject to any other legislation as mentioned in Article 2.2 of the BPR, it is covered by the definition of a biocidal product in the first indent of Article 3(1)(a) of BPR. It is therefore irrelevant whether the biocidal function is primary or secondary.

Decision tree

The following decision tree has been developed to help decide whether an object treated with or intentionally incorporating one or more biocidal products is a treated article or a biocidal product

As a first step, it is important to decide whether the object is a "substance or a mixture" or an "article". According to Article 3(1)(a) of the BPR, a substance or mixture only needs to have an intended biocidal function to fulfil the definition of a biocidal products, irrespective whether the biocidal function is primary or not. In contrast, an article is only considered a biocidal product when it has a *primary* biocidal function.

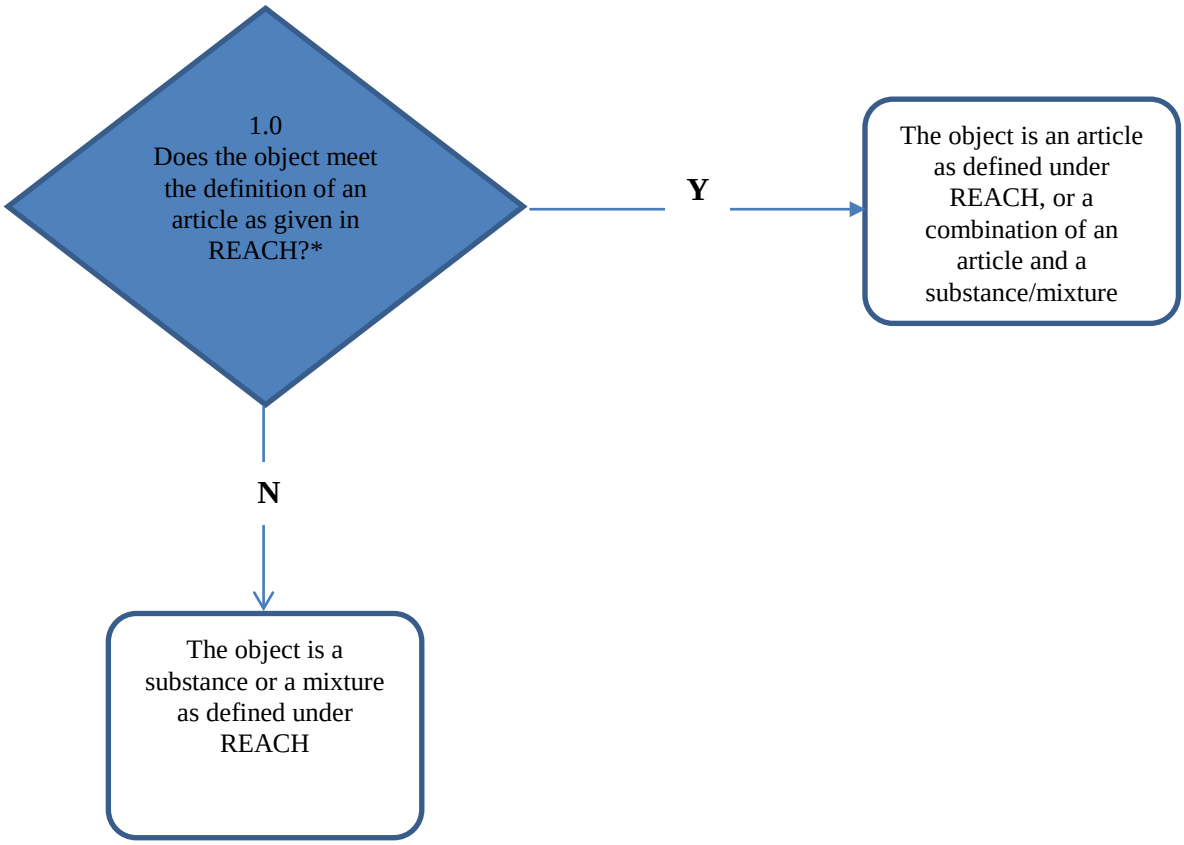
For the definition of substance, mixture and article, the BPR makes reference to the REACH Regulation[4]. According to this Regulation:

- Substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

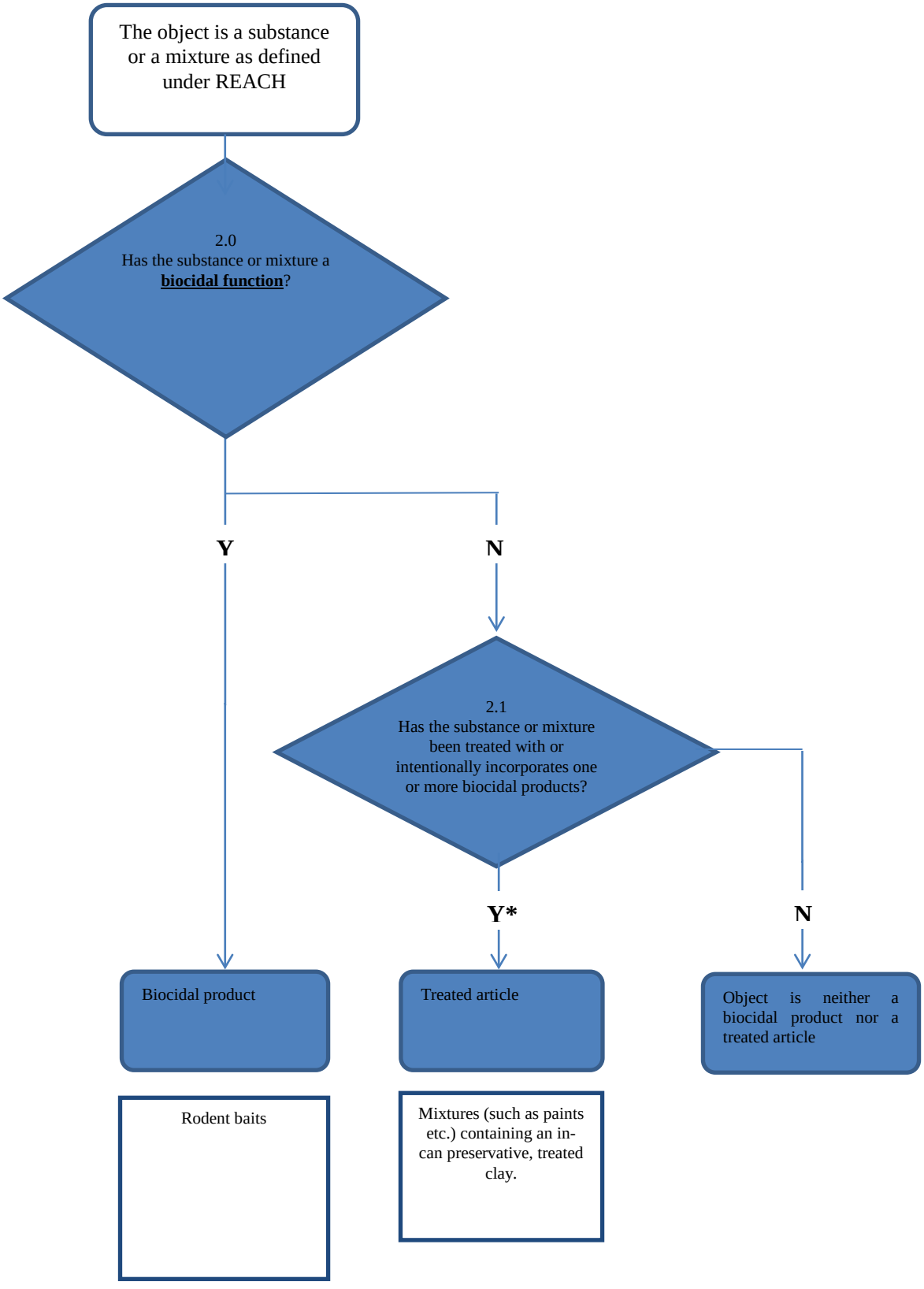
- Mixture: means a mixture or solution composed of two or more substances;

- Article: means 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.

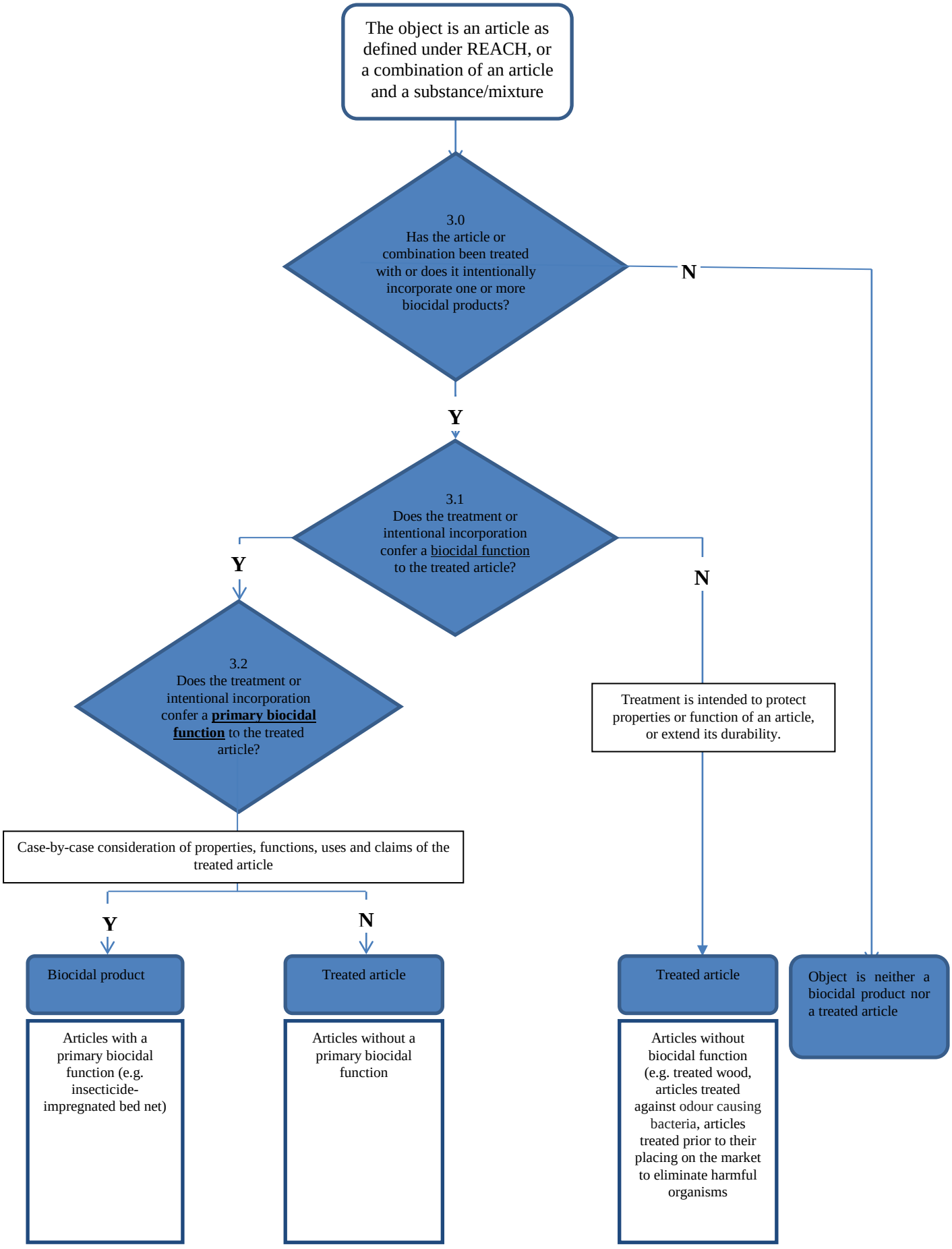
[4] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency. OJ L 396, 30.12.2006, p. 1.



*** ECHA guidance on requirements for substances in articles, in particular section 2, is available to assist stakeholders and competent authorities to decide whether an object is a substance, a mixture or an article, or a combination thereof.**
http://echa.europa.eu/documents/10162/13632/articles_en.pdf



*** If the substance incorporates a biocidal product, it is no longer a substance, but a mixture.**


The object is an article as defined under REACH, or a combination of an article and a substance/mixture
3.0 Has the article or combination been treated with or does it intentionally incorporate one or more biocidal products?
N
Y
3.1 Does the treatment or intentional incorporation confer a biocidal function to the treated article?
Y
N
3.2 Does the treatment or intentional incorporation confer a primary biocidal function to the treated article?
Treatment is intended to protect properties or function of an article, or extend its durability.
Case-by-case consideration of properties, functions, uses and claims of the treated article
Y
N
Biocidal product
Articles with a primary biocidal function (e.g. insecticide-impregnated bed net)
Treated article
Articles without a primary biocidal function
Treated article
Articles without biocidal function (e.g. treated wood, articles treated against odour causing bacteria, articles treated prior to their placing on the market to eliminate harmful organisms
Object is neither a biocidal product nor a treated article

Active substances

14. Question:

How should the requirement in Article 58(2) of BPR, that 'all active substances contained in the biocidal products' need to be approved or included in Annex I be understood?

Answer:

This should be understood to refer to the active substances contributing to the biocidal function(s) of the biocidal product(s) used to treat or intentionally incorporated into the treated article. Active substances, which do not contribute to the biocidal function(s), of the biocidal product(s) such as an in-can preservative contained in the biocidal product, are not covered by this requirement of Article 58(2). However, it should be noted that biocidal products used in the manufacturing of treated articles in the EU are subject to other requirements of BPR and can only contain in-can preservatives that are approved, included in Annex I or under evaluation in the review programme.

15. Question:

In Article 58(3)(c) of BPR, what does 'all active substances contained in the biocidal products' mean?

Answer:

This is to be understood to include all active substances which contribute to the biocidal function(s) of the biocidal product(s) that was used to treat or intentionally incorporated into the treated article.

As an example, if a claim is made regarding the biocidal property of treated wood (e.g. long-lasting wood protection against insects), the name of the active substance acting as wood preservative in the biocidal product would have to appear on the label of the treated article, but not the name of any in-can preservative contained in the biocidal product.

16. Question:

If a finished good incorporates a substance which is known to have some biocidal activity (e.g. substances included in Annex I of Regulation (EC) No 1451/2007), but which has been used for reasons unrelated to this biocidal activity (e.g. essential oils, such as lavender oil, that may be used to perfume certain articles), must the substance be approved if the article is placed on the EU market?

Answer:

No, Article 58 of BPR relates to treated article that were treated with a biocidal product. This means that the product (and hence the active substance) must have been applied with the intention of conferring a biocidal property or function.

However, in case of controls by competent authorities, the burden of the proof will be on the person placing the treated article on the market to demonstrate that a substance with potential biocidal activity was incorporated for purposes other than its biocidal activity.

ACTIVE SUBSTANCE APPROVAL

Relevant product-type and use

17. Question:

How wide or narrow is the notion of 'relevant use' to be defined? As it is listed in addition to the PT, it seems that the approval for the appropriate PT is not sufficient in the absence of a mentioning of the particular use in the approval.

Answer:

The assessment of an active substance is done on the basis of a representative product, and the active substance is approved if at least one biocidal product containing that substance is expected to meet the criteria for authorisation. This implies that, as a general rule, not all possible uses of an active substance are considered at the time of approval.

The current practice varies from product-type to product-type. In the case of wood preservatives, for which use classes are well codified, these use classes are considered in the assessment and the area of use is an element of the approval. For other product-types, such as insecticides or disinfectants, no such distinction between use classes is currently made in the active substance approval.

With the introduction of provisions for treated articles in the BPR, the basic principle that active substance approval is based on one or more representative biocidal products has not been changed. It is only possible to comprehensively assess uses in treated articles at the time of initial active substance approval where there is already a well-established and codified practice, such as for wood preservatives. For other product types there was no obligation for applicants to provide data on all possible uses in treated articles in the dossiers submitted under the review programme.

For other product-types, the approval of an active substance would generally also cover the use in treated articles. However, if concerns are identified during the assessment, restrictions or conditions can be established in the approval of active substance in relation to treated articles.

Concerning limitations on the possibility of the active substance to be used in treated articles, a similar approach as for the approval of the active substance for use in biocidal product is followed, i.e.

• Restrictions concerning the use of the active substance in treated articles are introduced only where a major concern is identified.

• In such cases, the approval will indicate in which categories of treated articles the active substance and biocidal products containing it can or, as appropriate, cannot be used.

• Major concern shall correspond to cases:

o where the active substance meets the exclusion criteria set in Article 5(1), but would benefit from a derogation to the exclusion on the basis of Article 5(2).

o When there are reasons for major concern linked to the nature of the critical effect, which in combination with certain foreseeable use pattern could pose such a risk to human health (the user of a treated article, the general public etc.), or to the environment, such as justifying a restriction on the use of the active substance and biocidal products containing it in treated articles.

In cases where, based on a case-by-case assessment, a concern has been identified which does not justify the limitation of uses in treated articles as described above, a provision on labelling of treated articles can be established in the approval.

18. Question:

How strictly shall the scope of the PTs be looked at? For example, the textile industry mentioned that they often use biocides in textiles to protect it as well as to prevent bad odours.

Answer:

The active substance shall have been approved for the PT for which the biocidal product(s) will exert a biocidal function in the treated article.

For example, if a textile has been treated with a biocidal product which will preserve the article as well as prevent the development of bad odours, the active substance(s) shall have been approved for product-type 9, as this product-type covers both products used for the preservation of fibres as well as products which antagonise the settlement of micro-organisms and thus prevent the development of odours.

However, if a textile has been treated with a biocidal product preserving the article as well as giving it a disinfecting function, the active substance(s) shall have been approved for both product-types 2 and 9, as product-type 2 covers products used to be incorporated in textiles with the purpose of producing treated articles with a disinfecting function, whilst product-type 9 covers products used for the preservation of fibres.

SCOPE

Complex articles

19. Question:

Does the concept of treated articles cover only treatments made on the finished article, or also treatments made on components further back in the supply chain? If so, how far back in the supply chain have possible treatments to be identified?

For example, a table is manufactured outside the EU from composite wood, and the wood is bound with glue containing an in-can preservative (also manufactured outside the EU) – does the preservative have to be approved if the table is then placed on the EU market? Or, electrical components within a television were treated with a biocidal product to give them protection against the growth of fungi (and no other part of the TV was treated). Does the active substance in the fungicide have to be approved in the EU?

Answer:

This question has been addressed in detail in a document discussed with the Competent Authorities of EU Member States in September 2014. This text (revised following discussion) is included in Appendix 3.

Article 3(1) (l) of the BPR defines a treated article as '…any substance, mixture or article which has been treated with, or intentionally incorporates one or more biocidal products'. As indicated in Article 58 (2) to (4), the provisions of Article 58 apply to treated articles in the form in which they are placed on the EU market (in the following also referred to as "finished goods").

Against this background, it is evident that any finished good that has, as such, been treated with or intentionally incorporates a biocidal product qualifies as a treated article. On the other hand, treatment with or incorporation of a biocidal product can happen at any point during the manufacturing process. The definition of a treated article implies that the treatment with or incorporation of a biocidal product is made with the intention of conferring a biocidal property (or even a biocidal function) to the treated article, and can thus be expected to lead to a beneficial and desired effect in the finished good (e.g. protecting it from bio-degradation during storage or use). Following this logic, the scope of treated articles shall exclude such biocidal treatments or incorporation of biocides in a substance, mixture or article, or individual constituents thereof, which were made in the course of manufacturing merely in order to perform a specific biocidal function at that stage of the process, but which will not have an intended biocidal effect in the finished good as placed on the EU market.

In the case of "complex" articles made up of different components and/or materials, it is unlikely that any treatment or incorporation of a biocidal product concerns uniformly all components/materials. Nevertheless, one or several individual components/materials of a complex article may have been treated with or incorporate a biocidal product, and the biocidal property or function conferred to these components/materials may still be beneficial for the finished good as such (e.g. by increasing overall durability of the complex article). Such complex articles are to be regarded as treated articles.

Consequently, in relation to the examples given in the question, the residual presence of an in-can preservative in the glue used to make composite wood would not lead to a classification as a treated article, as this preservative was used to preserve the glue during storage, but not after its use to make the composite wood and the finished table. On the other hand, in the second example it appears that the protection against fungi is intended to be effective in the finished television set, which then would have to be considered a treated article.

20. Question:

What if only a small part of an article has been treated with or intentionally incorporates a biocidal product?

Answer:

The above interpretation also applies when only a small part of the finished good has been treated. If the treatment still has an intended biocidal function in the finished good, it is considered a treated article.

21. Question:

Which criteria could be applied to decide whether a finished good qualifies as a treated article?

Answer:

Indications whether a biocidal treatment has an intentional biocidal effect in a finished good can come from various elements, e.g. a claim concerning a biocidal property or function of the finished good or part thereof, the PT of the biocidal product used for the treatment and/or the concentration of the AS in the finished good.

22. Question:

Which role has a claim made on a finished good that is placed on the market in order to decide whether this good is a treated article?

Answer:

Claims on a finished good have an important role in indicating the intentional presence of a biocidal active substance that exerts a beneficial and intended effect.

In all cases where a claim concerning a biocidal function of a finished good is made, it is evident that the presence of a biocidal active substance in the finished good is intended by the manufacturer. Such goods will always be considered treated articles if, based on their overall characteristics, they do not qualify as a biocidal product themselves.

Also a claim concerning a biocidal property (i.e. that the finished good is protected against bio-degradation) clearly indicates an intentional presence of a biocidal active substance in the finished good. Moreover, also more implicit claims not directly referring to a biocidal action but e.g. concerning an increased durability or anti-odour properties of a textile can be taken as an indication that the presence of a biocidal active substance in

the good is intentional. In this case, the good would be considered a treated article unless the manufacturer/importer can present convincing justification that the claimed property is not due to a biocidal treatment that has led to the presence of the biocidal active substance.

If a biocidal active substance is present in the finished good the absence of a claim does, however, not automatically imply that the presence of the substance is unintentional. In such cases, other criteria like any available knowledge biocidal treatments made during production and on the uses and effective concentration of the active substance present need to be considered to decide whether the finished good qualifies as a treated article.

23. Question:

Which role has the PT of the biocidal product used for the treatment in order to decide whether a finished good is a treated article?

Answer:

Knowledge about the biocidal treatment and the biocidal product used for this purpose, including the PT it is authorised for, are the best source of information to determine whether the presence of a biocidal active substance in a finished good is intentional or not. However, if a known biocidal active substance is present in a finished good, and no information is available on the biocidal treatment that lead to this presence, the PT(s) for which an active substance is approved in the EU for may give indications about whether its presence is intentional or unintentional (see table below). It needs to be kept in mind that a substance with known biocidal activity may be present in a mixture or article for other purposes. If in the case of an enforcement action a biocidal use of the substance cannot be excluded, it will be the responsibility of the manufacturer/importer to justify that the substance is not present for biocidal purposes.

PT1 (human hygiene disinfectants)	Any chemical substance, mixture or article containing AS that fall into this PT are likely to be classified as biocidal products due to their use and the nature of the biocidal effect.
PT2 (disinfectants) **PT3** (veterinary hygiene products) **PT4** (food and feed area disinfectants)	Chemical substances or mixture containing AS that fall into this PT are likely to be classified as biocidal products due to their use and the nature of the biocidal effect. The incorporation of biocidal products of this PT in an article generally indicates an intended effect in the final good, and such articles, if not biocidal products by themselves, would qualify as treated articles.
PT5 (drinking water disinfectants)	Any chemical substance, mixture or article containing AS that fall into this PT are likely to be classified as biocidal products due to their use and the nature of the biocidal effect.
PT6 (preservatives for products during storage)	Biocidal products of PT6 are widely used to preserve products during storage. If the preserved good (a chemical substance, a mixture or an article) itself is placed on the market it qualifies as a treated article. An exceptional case are biocidal products (examples given in BPR, Annex V are rodenticides, insecticides, other baits, but in principle applicable to all BPs), preserved with PT6 preservatives, which qualify as biocidal products due to the

	presence of other biocidal active substances. Chemical substances and mixtures containing an in-can preservative may however be further used as ingredients in the manufacturing process of other finished goods. If the in-can preservative of such an ingredients in such cases has no further intended biocidal function later in the finished good, the residual presence of preservatives stemming from preserved ingredients should not qualify the finished good as a treated article. Also solid components used in the manufacture of a complex finished article may incorporate a PT6 preservative. In such cases it needs to be considered whether the preservation is relevant only during storage of this component (and not later in the finished article), or whether the preservation is also beneficial during the storage and possibly use of the finished article. In the first case, the finished article does not qualify as a treated article. in the latter case, the finished article would have to be considered a treated article.
PT7 (film preservatives)	The incorporation of biocidal products of this PT in a chemical substance or mixture or an article generally indicates an intended effect in the final good and such articles would qualify as treated articles.
PT8 (wood preservatives)	Biocidal products of PT8 (wood preservatives) will usually be used with the intention to provide long-term preservation of the wood, which would continue to be effective in the finished good, which would thus qualify as a treated article. Exceptions to this may be PT8 biocidal products used at saw-mill stage or during initial storage, which only serve to protect the wood at this stage from harmful organisms (e.g. short-term preservation of freshly cut wood with fungicides to prevent the discoloration caused by blue stain forming fungi until further processing), or curative treatments of wood before being manufactured into a finished good. Articles made at a later stage from wood that has undergone such treatments should not be considered treated articles.
PT9 (fibre, leather, rubber and polymerised materials preservative) **PT10** (construction material preservatives)	The incorporation of biocidal products of this PT in a chemical substance or mixture or an article generally indicates an intended effect in the final good and such articles would qualify as treated articles.
PT11 (preservatives for liquid-cooling and processing systems)	Biocidal products of PT 11 are likely to be used mainly in closed systems. Any traces of such preservatives in finished goods produced in the facility using these biocidal products should be considered unintentional and thus do not qualify the good as a treated article. However, preserved cooling or processing liquids as well as systems containing them, have to be considered treated articles when they are placed on the market.
PT12 (slimicides)	Biocidal products of PT12 are used in industrial processes to control slime growth at certain stages. Any traces of the AS in a finished good should be considered unintentional and thus do not qualify the good as a treated article. However, any liquids, fluids etc. containing slimicides, when placed themselves on the market, have to be considered treated articles.
PT13 (working or cutting fluid	Cutting or working fluids are used at certain stages of the production process. Any traces of such preservatives in finished goods produced in the facility using these biocidal products, should be considered unintentional and thus do not qualify the

preservatives)	good as a treated article. However, any working or cutting fluids containing preservatives, when placed on the market, have to be considered treated articles.
PT14-17, 20 (vertebrate pest control)	Any chemical substance, mixture or article containing AS that fall into these PTs are likely to be classified as biocidal products due to their use and the nature of the biocidal effect.
PT18 (insecticides) **PT19** (repellents and attractants) **PT21** (antifouling products) **PT22** (embalming and taxidermist fluids)	Chemical substances or mixture containing AS that fall into this PT are likely to be classified as biocidal products due to their use and the nature of the biocidal effect. The incorporation of biocidal products of this PT in an article generally indicates an intended effect in the final good, and such articles, if not biocidal products by themselves, would qualify as treated articles.

24. Question:

Which role has the concentration of the active substance in the finished good in order to decide whether this good is a treated article?

Answer:

In cases where information on the concentration of the active substance in the finished good is available, this may also provide useful indications. The use of biocidal products in certain production processes may leave traces of the biocidal active substances in the finished good. Preserved chemical mixtures that serve as ingredients for products will typically be diluted during production, so that the remaining concentration of in-can preservatives in the finished good is likely to be below the range where they would be effective. The presence of low, non-effective, concentrations of a biocide, together with the absence of any other indication that their presence in the finished good is intentional, may provide an indication that the finished good should not be considered as a treated article with regard to those active substances.

However, there may be cases where a biocidal active substance is present in a finished good at a concentration at which it could potentially exhibit biocidal activity, but this presence is still due to a use in an upstream step in production and the activity is neither intended by the manufacturer nor beneficial for the final article (e.g. the remaining presence of an in-can preservative in a dried glue or paint layer in/on an article, where preservation of the dried matrix is no longer required). In cases where an active substance in sufficient concentration to be active is present in an article or in a part thereof, it needs to be decided on a case-by-case basis, taking into account the nature and features of the article (including claims) and knowledge on the biocidal treatment made during production, whether the finished good qualifies as a treated article or not with regards to those active substances.

25. Question:

Could treated articles be defined as articles which, as a whole, contain more than 0.1% of the active substance, in analogy with REACH?

Answer:

Under REACH, the presence of a chemical identified as "substance of very high concern" and constituting ≥0.1% by weight of a given article triggers duties for the supplier to communicate information down the supply chain (REACH Regulation[5] Article 33). However, no trigger value for the application of the requirements of Article 58 of BPR for treated articles has been defined in this Regulation.

26. Question :

A sofa that has been treated with a fungicide to prevent growth of mould during shipping, , is that to be regarded as a treated article?

Answer:

The sofa has been treated with a PT 9 preservative in order to prevent deterioration of the finished good. This function is intended and remains a property of the sofa, regardless of whether the sofa is placed in conditions where mould can grow or not. Thus the sofa is to be regarded as a treated article.

Residues from production process

27. Question:

An article contains residues of a biocidal treatment that was used during the production process on some part of the manufacturing equipment. The treatment was not applied on the article itself. Must the active substance in this biocidal treatment be approved if the article is imported?

For example, paper could contain traces of a biocide that was applied as a slimicide to the printing equipment.

Answer:

No, a treated article is an article that is "treated with, or intentionally incorporates, a biocidal product". In this case the biocide has not been used with the intention to still have a biocidal function in the finished good. Therefore, for such an imported good, the active substance does not have to be approved for this use.

Exemption

28. Question:

What is the scope of the exemption foreseen in Article 58(1) of BPR?

Answer:

[5] insert reference REACH

The purpose of this provision is to exempt from the requirements of Article 58 all goods stored or contained in a premise or, respectively, transported in a container, which was fumigated or disinfected as the sole biocidal treatment, on the condition that no residues would be expected to remain from such treatment.

This provision can be relevant for instance for goods imported from third countries and which, by virtue of international trade agreements, have to undergo a specific treatment (i.e. fumigation or disinfection) before they can be placed on the EU market to prevent the transmission of organisms presenting a risk to animal or human health.

29. Question:

Does it cover all goods that were in the premises or containers when the fumigation or disinfection took place?

Answer:

The exemption covers all goods that were in the premises or containers which were fumigated or disinfected as the sole treatment with a biocide.

30. Question:

When can it be expected that no residues remain from such treatments?

Answer:

It is the responsibility of the person placing the treated article on the market to assess whether residues can be expected to remain from such treatment. If residues remain, the provisions of Article 58 will apply, if not, the exemption is applicable.

If the person placing the treated article on the market considers that no residues remain, but *ad hoc* controls indicate the presence of residues, the conditions for the exemption will not be met and the provisions of Article 58 apply.

LABELLING OF TREATED ARTICLES

Claim regarding the biocidal properties of a treated article

31. Question:

What is a claim regarding a biocidal property?

Answer:

In the context of Article 58(3) of the BPR, a claim is a statement indicating or implying:

- either that the treated article has a certain degree of protection against unwanted organisms. In this case, a claim thus refers to a biocidal property of the treated article.

- or that the treated article has a certain efficacy or action against unwanted organisms. In this case, a claim refers to a biocidal function of the treated article.

In cases where a claim is made, the efficacy of the treated article or of the treatment must be demonstrated in order for the claim to be substantiated (see also Question 33).

32. Question:

A treated article is marketed with a statement that it incorporates an active substance solely for the purpose of protecting the article. Does this article have to be labelled?

Answer:

This statement is a claim regarding the biocidal properties of the treated article. Such a statement would therefore trigger the labelling information listed under the second subparagraph of Article 58(3)

Examples of similar statements, which would be regarded as claim regarding the biocidal properties of the treated article, are given in the table below according to the type of substances (mainly preservatives) used to treat or intentionally incorporated in the treated article.

PT6: Preservatives for products during storage	Contains a preservative to control microbial deterioration.
PT7: Film preservatives	Contains a preservative to control microbial deterioration. Contains a preservative to control algal growth. Contains a preservative to protect the initial properties of the treated article.
PT8: Wood preservatives	Contains a preservative to control wood-destroying or wood-disfiguring organisms, including insects.
PT9: Fibre, leather, rubber and polymerised materials preservatives	Contains a preservative to control microbiological deterioration. Contains a preservative to antagonise the growth of micro-organisms on the surface of the treated article. Contains a preservative to hamper or prevent the development of odour on/in the treated article.
PT10: Construction material preservatives	Contains a preservative to control microbial deterioration. Contains a preservative to control algal growth.
PT11: Preservatives for liquid-cooling and processing systems	Contains a preservative to control harmful organisms such as microbes, algae and mussels.
Product-type 12: Slimicides	Contains a preservative to control slime growth.
Product-type 13:	Contains a preservative to control microbial deterioration

Working or cutting fluid preservatives	in fluids used for working or cutting metal, glass or other materials.
Product-type 18: Insecticides, acaricides and products to control other arthropods.	Contains an insecticide to to protect the material against deterioration. Contains an insecticide. Contains an acaricide.
Product-type 19: Repellents and attractants.	Contains an insect repellent to protect the material against deterioration.

It should be noted that, although all the above statements follow a similar structure ("Contains…"), any wording indicating incorporation or a treatment with a biocidal active substance to achieve a biocidal property of the treated article would constitute a claim triggering the labelling requirement.

Substantiated claims

33. Question:

What is to be understood by the term "where substantiated" in Article 58(3)(b) of BPR in relation to the biocidal property attributed to the treated article?

Answer:

'Where substantiated' is to be understood as 'where supported with proof or evidence'. In other words, the label should not provide information on the biocidal property attributed to the treated article, when the importer or manufacturer of the treated article is not able to support the claim through appropriate data. The substantiation of a claim is even more important in cases where a biocidal function of the treated article is claimed.

The requirement that any claim made is clear, accurate and substantiated follows also from the provisions of Directive 2005/29/EC[6] on Unfair Commercial Practices.

Claims with public health relevance

34. Question:

What is a claim with public health relevance?

Answer:

[6] 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council

In the context of the BPR, a claim with public health relevance is a statement that a treated article is expected to provide benefits against pathogenic organisms of public health relevance if used as indicated or implied by the person placing the treated article on the market.

Claims with public health relevance cover claims that a treated article would protect users or others against specific pathogenic bacteria, viruses, fungi or other organisms such as E. coli, S. aureus, Salmonella sp., Streptococcus sp., influenza H1N1 virus, and diseases vectors, such as ticks or mosquitoes.

Claims with public health relevance deserve a greater level of scrutiny because of their potential impact on public health. Thus, when such claims are made on a treated article, they need to be considered, together with all other individual properties and functions and the intended uses of the treated article, in the decision as to whether the treated article may have a primary biocidal function (see also Questions 11 and 12)[7].

Antibacterial claim

35. Question:

Is it acceptable to indicate 'antibacterial' on the label of a treated article?

Answer:

Claims such as:

- Antibacterial
- Fight germs
- Kills 99% bacteria
- Provide antibacterial protection
- Control fungus.

indicate that the treated article has a biocidal function. Such claims are acceptable provided they are substantiated as indicated in Article 58(3) of the BPR.

However, taking into account all other individual properties, functions and intended uses of the treated article, this biocidal function could be considered as a primary biocidal function.

In such cases, the treated article would be regarded as a biocidal product and would have to be authorised as such.

[7] The UK disagrees, based on the text of BPR, that the presence of public health claims is a relevant factor in determining whether a treated article has a primary biocidal function, and hence is a biocidal product. Therefore the UK disagrees with this paragraph of the guidance document

On the other hand, a statement such as 'contains a preservative against microbial deterioration' would be regarded as a claim regarding the biocidal properties of the treated article, but not about the biocidal function of the treated article.

More than one active substance

36. Question:

If the treated article has been treated with biocidal product(s) containing more than one active substance, should the label refer to all of them, or only to the one(s) that gave rise to the claim or for which the conditions for the approval of the active substance so require?

Answer:

When a treated article has been treated with biocidal product(s) containing more than one active substance, the label only has to mention those substances that contribute to the biocidal properties claimed, or for which the conditions for the approval require such labelling (see also Question 15).

Nanomaterial

37. Question:

If the conditions of the first subparagraph of Article 58(3) are not fulfilled, but the biocidal product contains a nanomaterial, is it so that there is no obligation to indicate this on a label?

Answer:

The obligation to indicate on the label that a treated article contains a nanomaterial only applies in cases where a claim is made that the treated article has a biocidal property or when it contains an active substance for which the conditions of approval require labelling.

Obligation of companies further down the supply chain

38. Question:

What are the obligations of the companies further down the supply chain? Does the labelling have to remain on the treated article throughout its life cycle?

Answer:

Companies further down the supply chain have no further obligations apart from suppliers of treated articles, which in accordance with Article 58(5) have to respond within 45 days to consumer requests concerning the biocidal treatment of the treated article.

However, if a treated article is incorporated in a new product, which itself will then meet the definition of a treated article, the person responsible for placing this product on the market needs to comply to the labelling provisions of article 58(3) in cases where those provisions are triggered.

Location of the claim

39. Question:

Where does a biocidal claim have to be made for labelling to be required? For example, a treated article is marketed without mention of biocidal properties, but the accompanying technical documentation mentions that it has been treated with a biocide with the purpose to confer a biocidal property.

Answer:

BPR does not specify where a claim has to be made in order for labelling to be required. Thus, if the claim is included as part of the technical specifications of an article, this would trigger the labelling requirement if a biocidal property is claimed.

Location of the label

40. Question:

Where does the label for a treated article have to be placed – must it be affixed to the article itself or can it be placed on instructions or packaging?

Answer:

The decision where to place the label will be a case-by-case decision depending on the individual features of the treated article in question. Article 58(6) implies that whenever possible, the label should be affixed to the treated article itself, but provided that "Where necessary because of the size or the function of the treated article, the labelling shall be printed on the packaging, on the instructions for use or on the warranty (…) unless [the] Member State provides otherwise". It is thus a matter of judgement for the person responsible for the placing on the market whether the label can be placed on the treated article itself, in which case it has to be placed there, or must be put on the packaging or instructions.

Responsibility of the person placing the treated article on the market

41. Question:

How is the relationship between paragraph 3 and paragraph 4 of Article 58 of BPR to be understood? Who decides if labelling is in any case necessary to protect human beings and the environment?

Answer:

This is the responsibility of the person placing the treated article on the market to decide, in view of the available information on the hazard profile of the active substance(s) and

the foreseeable uses of the treated article, on the possible risks that the treated article may pose to human or animal health or the environment, and whether any relevant instructions for use should be provided to the end-user to minimise that risk.

This also follows from the provisions of Directive 2001/95 on the General Safety of Products.

Labelling of intermediate or raw materials

42. Question:

Do intermediates or raw materials treated with or intentionally incorporating a biocidal product need to be labelled?

Answer:

If these intermediate or raw materials meet the definition of a treated article, the provisions of Article 58 will apply to them if they are themselves placed on the EU market. This means that not only the provisions on labelling will need to be observed, but also those regarding the active substance contained in the biocidal product used to treat these intermediates or raw materials.

43. Question:

Article 58(6) is very limited in the possibilities to submit the information required by the labelling provisions for treated articles. Apart from a label on the treated article itself, only use-instructions or warranty papers are mentioned as alternatives. However, for intermediate or raw materials supplied in the context of business-to-business transactions, direct labelling may not be practical and use-instructions or warranty papers are not usually available. Can transport or commercial papers be used to transmit the required information?

Answer:

The reference to use instructions or warranty paper as a means to fulfil the labelling requirements seems to have been devised with mainly goods geared towards private or professional end-users in mind. Where intermediate or raw materials meet the definition of a treated article and labelling requirements apply, it appears appropriate to interpret the term "use-instructions" widely and allow the inclusion of the required information in any documentation accompanying the intermediate/raw material.

Sector-specific equivalent labelling requirements

44. Question:

What needs to be done in terms of identifying those cases where sector-specific equivalent labelling requirements already exist?

Answer:

It is for the person placing the treated article on the market and relying on sector-specific legislation to prove, in case of enforcement action, that the labelling requirements for treated articles are adequately addressed through this sector-specific legislation, i.e. that at least equivalent information is provided.

Treated article designed and manufactured to meet a specific order

45. Question:

How is the provision in Article 58(6) of BPR relating to treated article designed and manufactured to meet a specific order to be understood?

Answer:

This provision only applies to treated articles that are not produced as a part of series. It offers some degree of flexibility as to the means that can be used to convey the information to be provided to the customer, but not on the content of this information.

Expiry date

46. Question:

Is it mandatory or acceptable to indicate an expiry date on the label of a treated article as its biocidal function might be limited in time due to, for instance, washing off of the active substance contained in it?

Answer:

There is no legal requirement to indicate an expiration date on the treated article. Manufacturers of the article can however do it at their own will if they deem it useful.

Placing on the market

47. Question:

How is 'placing on the market' to be interpreted in the context of the labelling requirements of Article 58(3) – is labelling required for each individual treated article placed on the market after 1 September 2013, or only if a new product type or model is placed on the EU market for the first time?

Answer:

Placing on the market[8] is the initial action of making a product available for the first time on the EU market, with a view to distribution or use in the Community. The concept of

[8] For more information on the concept of 'placing on the market', please refer to http://ec.europa.eu/enterprise/policies/single-market-goods/files/blue-guide/guidepublic_en.pdf

placing on the market refers to each individual product, not to a type of product, and whether it was manufactured as an individual unit or in series. This means that even though a product model or type has been marketed or sold before the BPR has entered into force, individual units of the same model or type, which are made available on the market after 1 September 2013 must comply with these new requirements.

TRANSITIONAL ARRANGEMENTS FOR TREATED ARTICLES

The transitional rules concerning treated articles are laid down in Article 94 of the BPR. This article was recently modified by Regulation (EU) No 334/2014 amending Regulation (EU) No 528/2012, and the below guidance is based on the amended text.

48. Question:

From when does the requirement of Article 58(2) apply that a treated article may only be placed on the market if all active substances used for treating it are approved or included in Annex I of BPR?

Answer:

Up to 1 March 2017, treated articles placed on the EU market may still have been treated with biocidal active substance neither approved/included in Annex I of BPR, nor under evaluation in the review programme.

From 1 March 2017, treated articles may only be placed on the EU market if all the biocidal active substances they have been treated with are either approved/included in Annex I of BPR, and thus comply with Article 58(2), or are under evaluation in the review programme.

49. Question:

An article is treated with a biocide containing an active substance that is not yet approved in the EU, but is included in the review programme for the relevant product type. Can this article continue to be marketed until a decision is taken on the approval/non-approval of the active substance? What happens after such a decision is taken?

Answer:

A treated article can continue to be placed on the market after 1 March 2017 if the relevant active substance/PT combination is included in the review programme (i.e. the work programme referred to in Article 89(1)) by that date.

In case a decision is taken after 1 September 2016 not to approve the active substance for the relevant PT, the treated article can only be placed on the market for another 180 days after this decision.

In case a decision is taken to approve the substance for the appropriate PT (and use, where relevant), the transitional rules continue to apply until the date of approval (which, for active substances in the review programme, is ca. two years later than the decision). This may be relevant in cases where certain provisions concerning the use of the active substance for treated articles are included in the decision, e.g. labelling requirements or use restrictions.

50. Question:

For the transitional rules of Article 94 to apply, is it relevant whether the treated article was already on the market when the BPR came into force (1 September 2013)?

Answer:

According to the amended text provided by Regulation (EU) No 334/2014 it is not necessary that a treated article was already on the EU market on 1 September 2013 for the transitional rules to apply.

51. Question:

An existing active substance, used to make a treated article, is subject to a non-approval decision. As far as one knows, no new application will be made to support the active substance. What are the consequences for the treated article?

Answer:

If a non-approval decision for an active substance is taken before 1st September 2016, the treated article can continue to be placed on the market until 1 March 2017.

For treated articles manufactured in the EU, the non-approval decision will however also affect the availability of biocidal products that can be used for the treatment. Biocidal products containing an active substance subject to a non-approval decision can only be made available on the market for 12 month after the date of such a decision, and be used for 18 month after the date of the decision.

If a decision on the non-approval of an active substance is taken after 1 September 2016, the treated article can only be placed on the market for another 180 days after the decision.

Considering that biocidal products containing an active substance subject to a non-approval decision can be made available on the market and used for another 12/18 months, respectively, after the date of the decision, it will in this case still be possible to manufacture treated articles in the EU. However, after expiry of the 180 day-deadline for the placing on the market of the treated article in the EU, such treated articles can only be manufactured for export.

Please note that the deadlines for treated articles concern explicitly the placing on the market of treated articles, i.e. the first making available on the market of an individual product. Any later making available on the market (i.e. further supply and distribution) and use of this same individual treated article is not covered by the scope of the BPR.

52. Question:

What if a treated article has been treated with or incorporates an active substance for which an application for approval has been made pursuant to Article 94? Can it already be placed on the market during the review of the active substance?

Answer:

Until 1 March 2017, Article 94 provides a general derogation for treated articles treated with or incorporating active substances which are neither approved, included in Annex I, or under evaluation in the review programme.

If an application for the approval of such an active substance for the relevant PT has been submitted before the 1 September 2016, the treated article may still be placed on the market after 1 March 2017 until a decision is taken on the approval/non-approval of the active substance for this PT.

If an application for approval of such an active substance is submitted after 1 September 2016, a treated article that has been treated with it or intentionally incorporates it can only be placed on the market once the active substance has been approved for the relevant PT.

However, it should be noted that unless one of the derogations foreseen in BPR for the authorisation of biocidal products applies, it will not be possible to use in the EU in the manufacture of treated articles a biocidal product containing an active substance for which the submission will have been made pursuant to Article 94. This will only become possible once the new active substance is approved and the product authorised.

53. Question:

Why should a person responsible for placing on the market of a treated article be aware about the progress in assessing the active substance with which the article has been treated?

Answer:

Persons responsible for placing on the market a treated article should careful monitor the progress in assessment of the relevant active substances to be aware of upcoming decisions concerning them. In case of a non-approval decision, a strict deadline applies after which the treated article can no longer be placed on the market. But also in case on an approval decision, the approval may be subject to certain use restrictions or labelling obligations for treated articles may be prescribed.

54. Question:

Article 94 on the transitional measures concerning treated articles does not include specific provision for the labelling of treated articles. Is there a deadline when the labelling of treated articles has to comply with the provisions of Article 58(3)?

Answer:

The BPR does indeed not foresee transitional measures for the labelling of treated articles. This means that the requirement for labelling based on a claim made by the manufacturer in Article 58(3) applied from the date of coming into application of the BPR, i.e. 1 September 2013, and all treated articles placed on the EU market after this date have to comply with the labelling requirement.

It should be noted that the labelling provisions of article 58(3) concerns the "placing on the market", but not the subsequent supply, and that there is no mandatory labelling of all treated articles already present in the supply chain on 1 September 2013.

Labelling requirements imposed by conditions in the active substance approval apply from the date of approval. For substances evaluated in the frame of the review programme, this date, is specified in the approval decision and usually is two year after the issuing of the decision.

MISCELLANEOUS

Link with Article 95

55. Question:

Does Article 95 of the BPR apply to treated articles, i.e. can a mixture or article only be treated with or intentionally incorporate a biocidal product containing an active substance if the supplier has submitted a dossier or a letter of access to ECHA?

Answer:

No, the requirements on alternative suppliers in Article 95 do not directly apply to substances used only in treated articles governed by Article 58 of BPR. However, it does apply to substances placed on the EU market in biocidal products, or with the intention of being used in biocidal products, and thus may have an indirect effect for treated articles produced in the EU, as the biocidal products used need to comply with Article 95.

Packaging

56. Question:

For the purpose of the provisions on treated articles, is the packaging of a treated article regarded as part of the article itself?

Answer:

According to ECHA guidance for the REACH[9] Regulation, packaging does not become part of the packaged article, but remains a separate article.

However, packaging materials meeting themselves the definition of a 'treated article' have to comply with Article 58 of BPR when placed on the market.

Therefore, an importer placing on the EU market a treated article together with its packaging have to consider whether the packaging may constitute a treated article, and provisions of article 58 need to be observed.

57. Question:

Is primary and secondary packaging of products such as medicinal products, medical devices and cosmetics covered by the exemption for these products according to Article 2 (2), so that the provisions for treated articles under the BPR do not apply to the packaging?

Answer:

The BPR exempts treated articles from its scope if they are within the scope of certain other legislations. This means the primary and secondary packaging would be subject to BPR rules only in cases where the packaging of the products is not addressed by the rules governing this type of products.

It needs also to be kept in mind that if packaging materials treated with biocidal products are placed on the EU market before being used to package products exempt from the scope of BPR, they would be fully covered by the treated article rules of BPR.

Additional Information

58. Question:

Where can I find information on active substances approved for the use in biocidal products in the EU, the conditions and restrictions for use, and on substances under evaluation in the biocides review programme?

Answer:

In general, the European Chemicals Agency's webpage (http://echa.europa.eu/regulations/biocidal-products-regulation) contains a wealth of useful information in relation to biocides and treated articles.

In particular it provides a list of approved active substances (http://echa.europa.eu/en/regulations/biocidal-products-regulation/approval-of-active-substances/list-of-approved-active-substances) and the list of active substances and their

[9] REACH Guidance on requirements for substances in articles http://echa.europa.eu/documents/10162/13632/articles_en.pdf

suppliers (the so-called Article 95 list, http://echa.europa.eu/information-on-chemicals/active-substance-suppliers) which gives comprehensive information on all active substances for which a dossier has been submitted, covering both approved active substances and active substances under evaluation.

Moreover, the opinions of the Biocidal Products Committee (BPC) of ECHA on active substances are published on the BPC website, and may contain pertinent information for their use in treated articles (http://echa.europa.eu/web/guest/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval).

Additional questions can be addressed to the national helpdesks in individual EU Member States or the helpdesk of ECHA (see list of contact points at http://echa.europa.eu/support/helpdesks).

Appendix 1

Product Examples

The examples below are indicative and refer to the typical categorisation of a listed product group. The assessment of whether any individual product is a treated article, a biocidal product or neither of the two must be made on a case-by-case basis, taking into account all its characteristics.

Biocidal product	Treated article	Not a treated article
Disinfecting wipe	Article in which a disinfectant was incorporated to generate an antimicrobial surface (e.g. chopping board or equipment in the production of foodstuff)	Components or intermediate forms which were disinfected (which are not themselves placed on the EU market)
	An article which has been disinfected (in the form as it is placed on the EU market) to render it sterile or reduce contamination	
	Wooden article, or wooden components of a complex article, impregnated with an insecticidal wood preservative in order to protect it from becoming infested	Wooden components of a complex article, or an intermediate form of a wooden article (which are not themselves placed on the EU market) that have been treated with an insecticide (e.g. by fumigation) in order to remove a present infestation
	Wooden article treated with an insecticide (e.g. by fumigation) in order to remove a present infestation	
	Speciality paper incorporating a preservative in order to protect the finished article during use such as anti-mould treated papers	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
		Paper resulting from a production process where slimicides were used in order to avoid slime development in the paper machine and in the process water system
	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
		Paint, detergents, etc. containing an additive, and that additive had an in-can preservative added in order to protect its during storage, where this preservative has no further preserving function in the final product
Paints and coatings containing a fungicide to fight existing mould infestations (anti-mould paint)	Paints and coatings containing a preservative that extends the durability of the applied layer	
Paints and coatings intended to prevent microbial settlement and growth in order to provide a germ-free environment e.g. in hospitals		
	Complex articles containing e.g. paints, adhesives which contain a film preservative in order to protect the paint/glue layer during use of the article	
	Leather goods (shoes, seats) treated with a fungicide protecting the leather from decay	
	Textiles, or textile components of complex articles, treated with a preservative in order to increase durability of the fabric (also when used in multi-component articles)	
Mosquito net treated with an insecticide or insect repellent	Textiles, or textile components of complex articles, treated with an insecticide in order to protect the fabric from destruction by insects	
Insect-repelling bracelets	Clothes treated with an insect repellent	
	Clothes treated with a biocidal product in order to control odour-forming bacteria (also when used in multi-component articles)	
	Kitchen sponge treated to inhibit microbial growth during use	
	Plastic articles, or plastic components of complex articles, incorporating a preservative that protects them against harmful organisms and increases durability of the material	Plastic articles or plastic components of complex articles, made of ingredients (monomers, polymerisation aids, etc.) which contained preservatives in order to protect them during storage and manufacture, where these

		preservatives have no further function in the finished good
Antifouling paints	Fishing or aquaculture equipment and boats treated with antifouling products	
	Stuffed animals, which have been impregnated with taxidermist fluids containing (e.g. insecticides or preservatives)	

Appendix 2

Extracts from Regulation (EU) No 528/2012

Article 3
Definitions

1. For the purposes of this Regulation, the following definitions shall apply:

(a) ‘biocidal product’ means

— 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.

[…]

(l) ‘treated article’ means any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products;

Article 4
Conditions for approval

[…]

3. The approval shall specify the following conditions, as appropriate:

[…]

(d) manner and area of use including, where relevant, use in treated articles;

[…]

Article 58
Placing on the market of treated articles

1. This Article shall apply exclusively to treated articles within the meaning of Article 3(1)(l) that are not biocidal products within the meaning of Article 3(1)(a). It shall not apply to treated articles where the sole treatment undertaken was the fumigation or disinfection of premises or containers used for storage or transport and where no residues are expected to remain from such treatment.

2. 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 included in the list drawn up in accordance with Article 9(2), for the relevant product-type and use, or in Annex I, and any conditions or restrictions specified therein are met.

3. The person responsible for the placing on the market of 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.

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;

(ca) the name of all nanomaterials contained in biocidal products, followed by the word "nano" in brackets;

(d) 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.

This paragraph shall not apply where at least equivalent labelling requirements for biocidal products in treated articles to meet information requirements concerning those active substances already exist under sector-specific legislation.

4. Notwithstanding paragraph 3, the person responsible for placing on the market of a treated article shall label it with any relevant instructions for use, including any precautions to be taken, if this is necessary to protect humans and the environment.

5. Notwithstanding paragraph 3, the supplier of a treated article shall, upon request by a consumer, provide, within 45 days, free of charge, information on the biocidal treatment of the treated article.

6. The labelling shall be clearly visible, easily legible and appropriately durable. Where necessary because of the size or the function of the treated article, the labelling shall be printed on the packaging, on the instructions for use or on the warranty in the official language or languages of the Member State of introduction, unless that Member State provides otherwise. In the case of treated articles, which are not produced as part of a series, but rather designed and manufactured to meet a specific order, the manufacturer may agree other methods of providing the customer with the relevant information.

Article 94
Transitional measures concerning treated articles

1. By way of derogation from Article 58(2), a treated article treated with or intentionally incorporating one or more biocidal products containing only active substances that are under examination for the relevant product-type in the work programme referred to in Article 89(1) on 1 September 2016 or for which an application for approval for the relevant product-type is submitted by that date, or containing only a combination of such substances and active substances included in the list drawn up in accordance with Article 9(2) for the relevant

product-type and use or included in Annex I, may be placed on the market until one of the following dates:

(a) in the case of a decision adopted after 1 September 2016 to reject the application for approval of, or not to approve, one of the active substances for the relevant use, the date falling 180 days after such a decision;

(b) in other cases, the date of approval for the relevant product-type and use of the last active substance to be approved and contained in the biocidal product.

2. By way of further derogation from Article 58(2), a treated article treated with or intentionally incorporating one or more biocidal products containing any active substances other than those referred to in paragraph 1 of this Article or those included in the list drawn up in accordance with Article 9(2) for the relevant product-type and use or included in Annex I, may be placed on the market until 1 March 2017.

ANNEX V

BIOCIDAL PRODUCT-TYPES AND THEIR DESCRIPTIONS AS REFERRED TO IN ARTICLE 2(1)

MAIN GROUP 1: Disinfectants

These product types exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar products.

Product-type 1: Human hygiene

Products in this group are biocidal products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp.

Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals

Products used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs.

Usage areas include, inter alia, swimming pools, aquariums, bathing and other waters; air conditioning systems; and walls and floors in private, public, and industrial areas and in other areas for professional activities.

Products used for disinfection of air, water not used for human or animal consumption, chemical toilets, waste water, hospital waste and soil.

Products used as algaecides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials.

Products used to be incorporated in textiles, tissues, masks, paints and other articles or materials with the purpose of producing treated articles with disinfecting properties.

Product-type 3: Veterinary hygiene

Products used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products or with anti-microbial function.

Products used to disinfect the materials and surfaces associated with the housing or transportation of animals.

Product-type 4: Food and feed area

Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed (including drinking water) for humans and animals.

Products used to be incorporated into materials which may enter into contact with food.

Product-type 5: Drinking water

Products used for the disinfection of drinking water for both humans and animals.

MAIN GROUP 2: Preservatives

Unless otherwise stated these product-types include only products to prevent microbial and algal development.

Product-type 6: Preservatives for products during storage

Products used for the preservation of manufactured products, other than foodstuffs, feedingstuffs, cosmetics or medicinal products or medical devices by the control of microbial deterioration to ensure their shelf life.

Products used as preservatives for the storage or use of rodenticide**,** insecticide or other baits.

Product-type 7: Film preservatives

Products used for the preservation of films or coatings by the control of microbial deterioration or algal growth in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works.

Product-type 8: Wood preservatives

Products used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms, including insects.

This product type includes both preventive and curative products.

Product-type 9: Fibre, leather, rubber and polymerised materials preservatives

Products used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products by the control of microbiological deterioration.

This product-type includes biocidal products which antagonise the settlement of micro-organisms on the surface of materials and therefore hamper or prevent the development of odour and /or offer other kinds of benefits.

Product-type 10: Construction material preservatives

Products used for the preservation of masonry, composite materials, or other construction materials other than wood by the control of microbiological, and algal attack.

Product-type 11: Preservatives for liquid-cooling and processing systems

Products used for the preservation of water or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels.

Products used for the disinfection of drinking water or of water for swimming pools are not included in this product type.

Product-type 12: Slimicides

Products used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, porous sand strata in oil extraction.

Product-type 13: Working or cutting fluid preservatives

Products to control microbial deterioration in fluids used for working or cutting metal, glass or other materials.

MAIN GROUP 3: Pest control

Product-type 14: Rodenticides

Products used for the control of mice, rats or other rodents, by means other than repulsion or attraction.

Product-type 15: Avicides

Products used for the control of birds, by means other than repulsion or attraction.

Product-type 16: Molluscicides, vermicides and products to control other invertebrates

Products used for the control of molluscs, worms and invertebrates not covered by other product types, by means other than repulsion or attraction.

Product-type 17: Piscicides

Products used for the control of fish, by means other than repulsion or attraction.

Product-type 18: Insecticides, acaricides and products to control other arthropods

Products used for the control of arthropods (e.g. insects, arachnids and crustaceans**),** by means other than repulsion or attraction.

Product-type 19: Repellents and attractants

Products used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds, fish, rodents), by repelling or attracting, including those that are used for human or veterinary hygiene either directly on the skin or indirectly in the environment of humans or animals.

Product-type 20: Control of other vertebrates

Products used for the control of vertebrates other than those already covered by the other product-types of this main group, by means other than repulsion or attraction.

MAIN GROUP 4: Other biocidal products

Product-type 21: Antifouling products

Products used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water.

Product-type 22: Embalming and taxidermist fluids

Products used for the disinfection and preservation of human or animal corpses, or parts thereof.

ANNEX VI

COMMON PRINCIPLES FOR THE EVALUATION OF DOSSIERS
FOR BIOCIDAL PRODUCTS

[…]

14. A risk assessment on the active substance present in the biocidal product shall always be carried out. If there are, in addition, any substances of concern present in the biocidal product then a risk assessment shall be carried out for each of these. The risk assessment shall cover the proposed normal use of the biocidal product, together with a realistic worst-case scenario including any relevant production and disposal issue. The assessment shall also take account of how any "treated articles" treated with or containing the product may be used and disposed of. Active substances that are generated in-situ and the associated precursors shall also be considered.

[…]

Appendix 3

CA-Sept14-Doc.6.1 (revision of Dec. 2014)

EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
Directorate A – Green economy
ENV.A.3 - Chemicals

NOTE FOR DISCUSSION WITH COMPETENT AUTHORITIES FOR BIOCIDAL PRODUCTS

Subject: Treated articles

This document is an attempt to provide guidance in the interest of consistency, and has been drafted by the Commission services responsible for biocidal products with the aim of finding an agreement with all or a majority of the Member States' Competent Authorities for biocidal products. Please note, however, that Member States are not legally obliged to follow the approach set out in this document, since only the Court of Justice of the European Union can give authoritative interpretations on the contents of Union law.

1. Background and purpose of the document

Concerns were raised by various stakeholders (trade and industry associations, third country governments; see document CA-March14-Doc.6.1) that the current interpretation of the BPR provisions on treated articles as laid down in the Note for Guidance[10]: will pose serious practical problems for business operators.

To allow successful implementation of Article 58 of the BPR, it is necessary to ensure that it is practically possible for business operators to comply with the rules, and for enforcement authorities in the MSs to assess compliance. Therefore the Commission has critically reviewed the interpretation currently provided in the Note for Guidance and proposes the following understanding and approach for the implementation of Article 58, which is considered appropriate to maintain a high level of consumer protection while at the same time decreasing the burden on business operators.

[10] CA-Sept13-Doc.5.1.e, *Frequently asked questions on treated articles*, endorsed by the CA meeting in September 2013,

2. Proposed approach

Article 3(1) (l) of the BPR defines a treated article as '…any substance, mixture or article which has been treated with, or intentionally incorporates one or more biocidal products'. As indicated in Article 58 (2) to (4), the provisions of Article 58 apply to treated articles in the form in which they are placed on the EU market (in the following also referred to as "finished goods").

The definition of "treated with or intentionally incorporates" in Article 3 implies that the treatment with or incorporation of a biocidal product is made with the intention to confer a biocidal property (or even a biocidal function) to the treated article and would thus lead to a beneficial and desired effect in the finished good (e.g. protecting it from bio-degradation during storage or use). Following this notion of "treated with or intentionally incorporating", it is appropriate to exclude biocidal treatments or incorporation of biocides in a substance, mixture or article, or individual constituents thereof, which were made in the course of manufacturing merely in order to perform a specific biocidal function at that stage of the process, but which will not have an intended biocidal effect in the finished good as placed on the EU market.

In the case of "complex" articles made up of different components and/or materials, it is unlikely that the treatment or incorporation of a biocidal product concerns uniformly all components/materials. Nevertheless, one or several individual components/materials of a complex article may have been treated with or incorporate a biocidal product, and the biocidal property or function conferred to these components/materials may still be beneficial for the finished good as such (e.g. by increasing overall durability of the complex article). Such complex articles should also be regarded as treated articles.

3. Criteria to identify treated articles

In practice, the decision whether a finished good is a treated article will have to be taken principally on two levels: firstly by the person responsible for placing the good on the EU market (typically the manufacturer or the importer), and secondly by the enforcement authorities responsible for checking compliance with the rules applicable to a certain good. Indications whether a biocidal treatment has an intentional biocidal effect in a finished good can come from the criteria listed below. They can be used on both of these levels, but probably to varying extents, as not all the relevant information may be available on each of these levels. A decision on whether a good placed on the EU market intentionally incorporates a biocidal product and thus is considered a treated article will always have to take into account all characteristics of the article (including claims) and any available knowledge on the biocidal treatment made during production.

Important elements to consider for such a decision are:

i) Claims concerning a biocidal property or function of the finished good or part thereof:

Claims on a finished good have an important role in indicating the intentional presence of a biocidal active substance that exerts a beneficial and indented effect.

In all cases where a claim concerning a biocidal function of a finished good is made, it is evident that the presence of a biocidal active substance in the finished good is intended by the manufacturer. Such goods will always be considered treated articles, if, based on their overall characteristics, they do not qualify as a biocidal product themselves.

Also a claim on a biocidal property (i.e. that the finished good is protected against bio-degradation) clearly indicates an intentional presence of a biocidal active substance in the finished good. Moreover, also more implicit claims not directly referring to a biocidal action but e.g. concerning an increased durability or anti-odour properties of a textile can be taken as an indication that the presence of a biocidal active substance in the good is intentional. In this case, the good would be considered a treated article unless the manufacturer/importer can present convincing justification that the claimed property is not due to the biocidal treatment that has led to the presence of the biocidal active substance.

If a biocidal active substance is present in the finished good, the absence of a claim does not automatically imply that the presence of the substance is unintentional. In these cases, other criteria like the available knowledge on the biocidal treatment made during production, on the uses and effective concentration of the active substance present, its concentration, need to be considered to decide whether the finished good qualifies as a treated article.

ii) The PT of the biocidal product used for the treatment:

Knowledge about the biocidal treatment and the biocidal product used for this purpose, including the PT it is authorised for, are the best source of information to determine whether the presence of a biocidal active substance in a finished good is intentional or not. However, if a biocidal active substance is present in a finished good, and no information is available on the biocidal treatment that lead to this presence, the PT(s) for which an active substance is approved in the EU may give indications about whether its presence is intentional or unintentional (see table below).

PT1 (human hygiene disinfectants)	Any chemical substance, mixture or article containing AS that fall into this PT are likely to be classed as biocidal products due to their use and the nature of the biocidal effect.
PT2 (disinfectants) **PT3** (veterinary hygiene products) **PT4** (food and feed area disinfectants)	Chemical substances or mixture containing active substance that fall into this PT are likely to be classed as biocidal products due to their use and the nature of the biocidal effect. The incorporation of biocidal products of this PT in an article generally indicates an intended effect in the final good, and such articles, if not biocidal products by themselves, would qualify as treated articles
PT5 (drinking water disinfectants)	Any chemical substance, mixture or article containing active substance that fall into this PT are likely to be classed as biocidal products due to their use and the nature of the biocidal effect.

PT6 (preservatives for products during storage)	Biocidal products of PT6 are widely used to preserve products during storage. If the preserved good goods (a chemical substance or mixture or an article) itself is placed on the market it qualifies as a treated article. Chemical substances and mixtures containing an in-can preservative may however be further used as ingredients in the manufacturing process of other finished goods. If the in-can preservative of such an ingredient has no further intended biocidal function later in the finished good, the residual presence of preservatives stemming from preserved ingredients should not qualify the finished good as a treated article. Also solid components used in the manufacture of a complex finished article may incorporate a PT6 preservative. In such cases it needs to be considered whether the preservation is relevant only during storage of this component (and not later in the finished article), or whether the preservation is also beneficial during the storage and possibly use of the finished article. In the first case, the finished article does not qualify as a treated article. In the latter case, the finished article would have to be considered a treated article.
PT7 (film preservatives)	The incorporation of biocidal products of this PT in a chemical substance or mixture or an article generally indicates an intended effect in the final good and such articles would qualify as treated articles
PT8 (wood preservatives)	Biocidal products of PT8 (wood preservatives) will usually be used with the intention to provide long-term preservation of the wood, which would continue to be effective in the finished good, which would thus qualify as a treated article. Exceptions to this may be PT8 biocidal products used at saw-mill stage or during initial storage, which only serve to protect the wood at this stage from harmful organisms (e.g. short-term preservation of freshly cut wood with fungicides to prevent the discoloration caused by blue stain forming fungi until further processing), or curative treatments of wood before being manufactured into a finished good. Articles made at a later stage from wood that has undergone such treatments should not be considered treated articles.
PT9 (fibre, leather, rubber and polymerised materials preservative) **PT10** (construction material preservatives)	The incorporation of biocidal products of this PT in a chemical substance or mixture or an article generally indicates an intended effect in the final good and such articles would qualify as treated articles
PT11 (preservatives for liquid-cooling and processing	Biocidal products of PT 11 are likely to be used mainly in closed systems. Any traces of the active substance in finished goods produced in the facility using them should be considered unintentional

systems)	and thus do not qualify the good as a treated article. However, preserved cooling or processing liquids as well as systems containing them, have to be considered treated articles when they are placed on the market.
PT12 (slimicides)	Biocidal products of PT12 are used in industrial processes to control slime growth at certain stages. Any traces of the active substance in finished goods should be considered unintentional and thus do not qualify the good as a treated article. However, any liquids, fluids etc. containing slimicides, when placed themselves on the market, have to be considered treated articles.
PT13 (working or cutting fluid preservatives)	Cutting or working fluids are used at certain stages of the production process. Any traces of the preservative of such fluids in finished goods should be considered unintentional and thus do not qualify the good as a treated article. However, any working or cutting fluids containing preservatives, when placed on the market, have to be considered treated articles.
PT14-17, 20 (vertebrate pest control)	Any chemical substance, mixture or article containing active substance that fall into these PTs are likely to be classed as biocidal products due to their use and the nature of the biocidal effect.
PT18 (insecticides) **PT19** (repellents and attractants) PT21 (antifouling products) PT22 (embalming and taxidermist fluids)	Chemical substances or mixture containing active substance that fall into this PT are likely to be classed as biocidal products due to their use and the nature of the biocidal effect. The incorporation of biocidal products of this PT in an article generally indicates an intended effect in the final good, and such articles, if not biocidal products by themselves, would qualify as treated articles

iii) The concentration of the AS in the final article:

The use of some biocidal products in certain production processes is likely to leave only traces, of biocidal active substances in the finished good. Preserved chemical mixtures that serve as ingredients for products will typically be diluted during production, so that the remaining concentration of in-can preservatives in the finished good is likely to be below the range where they would be effective. The presence of such low, non-effective, concentrations of a biocide, together with the absence of any other indication that their presence in the finished good is intentional, may provide an indication that the finished good should not be considered as a treated article with regard to those active substances.

However, there may be cases where a biocidal active substance is present in a finished good at a concentration at which it could potentially exhibit biocidal activity, but this presence is still due to a use in an upstream step in production and the activity is neither intended by the manufacturer nor beneficial for the final article (e.g. the

remaining presence of an in-can preservative in a dried glue or paint layer in/on an article, where preservation of the dried matrix is no longer required). In cases where an active substance in sufficient concentration to be active is present in an article or in a part thereof, it needs to be decided on a case-by-case basis, taking into account the nature and features of the article (including claims) and knowledge on the biocidal treatment made during production, whether the finished good qualifies as a treated article or not with regard to those active substances.

The above criteria may be applied equally to finished goods manufactured in the EU, or such imported from non-EU countries. In the latter case, however, the available information on biocidal treatments made during manufacture may be less available and the onus is on the importer to provide justification that the presence of a biocidal active substance present in the good is not intentional. Enforcement authorities may encounter finished goods that are imported from third countries and which contain a chemical that has potentially a biocidal activity, but is not approved, included in Annex I to BPR or under review as a biocidal active substance in the EU. In such cases, it will need to be decided in the first place whether this presence is due to a biocidal use of the chemical, or whether it has been used for other purposes than that. If a biocidal use is suspected or established, the above criteria, apart from criterion ii) concerning PTs, can be used as indications on whether the good should be considered as a treated article or not. The onus is on the person responsible for the placing on the EU market to justify that the chemical has not been used for biocidal proposes, or if it has, that the remaining presence of the active substance it in the finished good is not intentional and that it confers no intended biocidal property. In case the finished good does not qualify as a treated, the chemical having potential biocidal activity does not need to be approved as biocidal active substance/included into Annex I/under review in EU.

Treatments that do not confer a biocidal property to the finished good, but remove manifest infestations (e.g. disinfection of an article, fumigation with an insecticide), may lead to significant residues when done on the finished good. Such goods should also qualify as treated articles. However, treatments made on intermediate forms, or on individual components of a complex article or a mixture are excluded, unless these are themselves placed on the EU market (e.g. supplied to another manufacturer).

The table annexed to this document[11] lists a number of examples illustrating the application of the above interpretation to different kinds of articles and mixtures.

[11] As an expanded version of the table originally presented in the annex to this document has been taken over into the present Note for Guidance on treated articles as Appendix 1, it is not again reproduced in this appendix.