EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
Directorate D - Water, Marine Environment & Chemicals
ENV.D.3 - Chemicals, Biocides and Nanomaterials

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 frequently asked questions.

DEFINITIONS

Treated article

1. Question: What is a treated article?

   Proposed Answer: 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'?

   Proposed Answer: 'Treating with' indicates that a biocidal product has been applied to a mixture or an article, or to a component thereof. Residues of the biocidal product might or might not remain in the mixture or article.

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

   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?

   Proposed Answer: 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?

Proposed Answer: An active substance is a substance or a micro-organism that has an action on or against 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?

   Proposed Answer: For the purpose of this note, 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 biocides review programme. An existing 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?

   Proposed Answer: A new active substance is an active substance which is not 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 not included in the review programme. An active substance which is existing for the product-types for which it is being evaluated in the review programme will be regarded as new for the product-types which are not included in the review programme.

PRINCIPLES

Biocidal property

7. Question: What is meant by ’property of an object’?

   Proposed Answer: The property of an object is a characterising quality or trait of the object.

8. Question: What is meant by ‘biocidal property of an article’?

   Proposed Answer: It means a property resulting from the fact that the article has been treated with or intentionally incorporates a biocidal product. Although a treated article with biocidal function (see below) always has a biocidal property, a treated article *without* biocidal function can nevertheless also have a biocidal property, e.g. increased durability of the article itself.

Biocidal function of a treated article

9. Question: What is meant by ‘the function of a treated article’?

   Proposed Answer: The function of a treated article is the intended purpose for which the article is supplied and acts by one or more means. A treated article has more than one function if it serves more than one purpose.

10. Question: What is meant by ‘a biocidal function’?

Proposed Answer: 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.

11. Question: What is a treated article with a biocidal function?

Proposed Answer: A treated article with a biocidal function is an article intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

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 incorporated into an article.

PT2:	Disinfectants and algaecides not intended for direct application to humans or animals.
PT4:	Food and feed area
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 with disinfecting properties, it is understood that the disinfectant will not act as a preservative of the treated article but would be expected to 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 article itself, or to confer a biocidal function to the treated article.

12. Question: How to determine whether a treated article has a biocidal function?

Proposed Answer: First of all, the article as such has to be supplied with the intended purpose of controlling harmful organisms. Secondly, one of the active substances in the 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 be biocidal products. Examples include disinfecting toilet wipes which are treated with a disinfectant, intended solely to control bacteria on toilets. The same applies to mosquito nets intended solely to control mosquitos, which are treated with insecticides or insect repellents. Such 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 removal of the bacteria from the toilet or physical prevention of mosquitos from approaching humans) may also contribute to that intended purpose.

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 article does 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 mosquito net treated with a textile preservative. According to BPR, such treated articles would still 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 incorporating a disinfectant. Such clothes have two intended purposes: To keep the body warm and to have an action against bacteria.

Primary biocidal function

13. Question: What is a primary biocidal function?

    Proposed 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 this context a primary biocidal function can be interpreted as a biocidal function of first rank, importance, or value compared to other functions.

14. Question: What does a "treated article with a primary biocidal function" refer to?

    Proposed Answer: It refers to a treated article that has one or more functions, among which, one is a biocidal function of first rank, importance, or value compared to the other functions of the treated article

15. 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?

    Proposed 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, based on consideration of the individual properties and functions of the article.

    A treated article which has one function only, and this function is biocidal, will always have a primary biocidal function.

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

    Such criteria include i.a. the concentration of the active substance in the treated article, 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, the claim 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 it would be species not harmful to the treated article itself.

    The influence of a claim on the decision whether a treated article has a primary biocidal function will depend on several aspects:

    - the prominence of the claim

If a claim made about a treated article is given greater prominence than other described properties or functions of that treated article, and if that claim refers to a biocidal function of the treated article, that function could be regarded as a primary biocidal function and the treated article as a biocidal product.

- whether the claim has public health relevance

In that respect, it is important to note that the objective of BPR is not only to protect public health and the environment from harmful effects of biocidal products and treated articles as such, but also from a variety of products or articles which are not sufficiently effective or which do not have the effect which consumers would be entitled to expect in view of the claim made and would then be used instead of the proper ones[1]. This is all the more important when the claim made is of public health relevance. As opposed to biocidal products, treated articles not covered by the second subparagraph of Article 3(1)(a) of BPR will not be subject to any efficacy assessment. Thus, when an averagely will-informed consumer gets the impression that a treated article has a biocidal function of public health relevance (i.e. an action against one or more organisms of public health relevance), in the interest of making the article subject to an efficacy assessment at product authorisation stage, that biocidal function could be regarded as a primary biocidal function and the treated article as a biocidal product.

16. Question: What rules govern a treated substance or mixture with a biocidal function? It is relevant whether the biocidal function is primary or not?

Proposed Answer: If a substance or mixture has any biocidal function, 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.

[1] 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

Decision tree

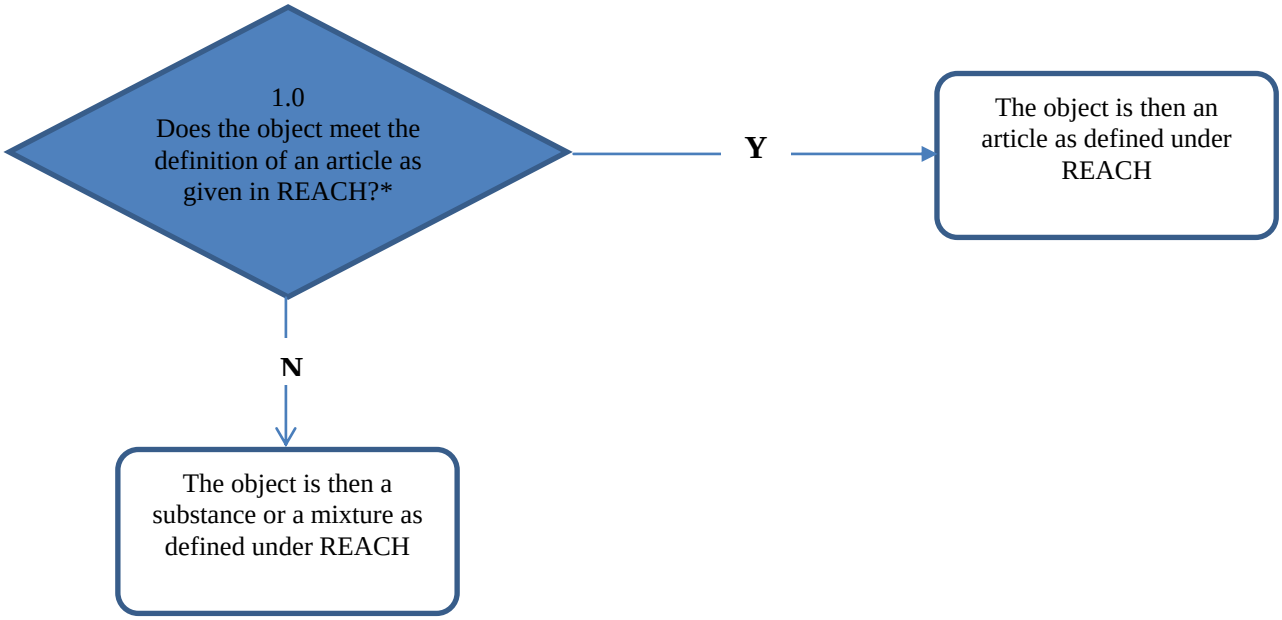
The following decision tree has been developed to help deciding whether an object treated with or intentionally incorporating one or more biocidal products is a treated article or a biocidal product

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 a 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[2]. 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;

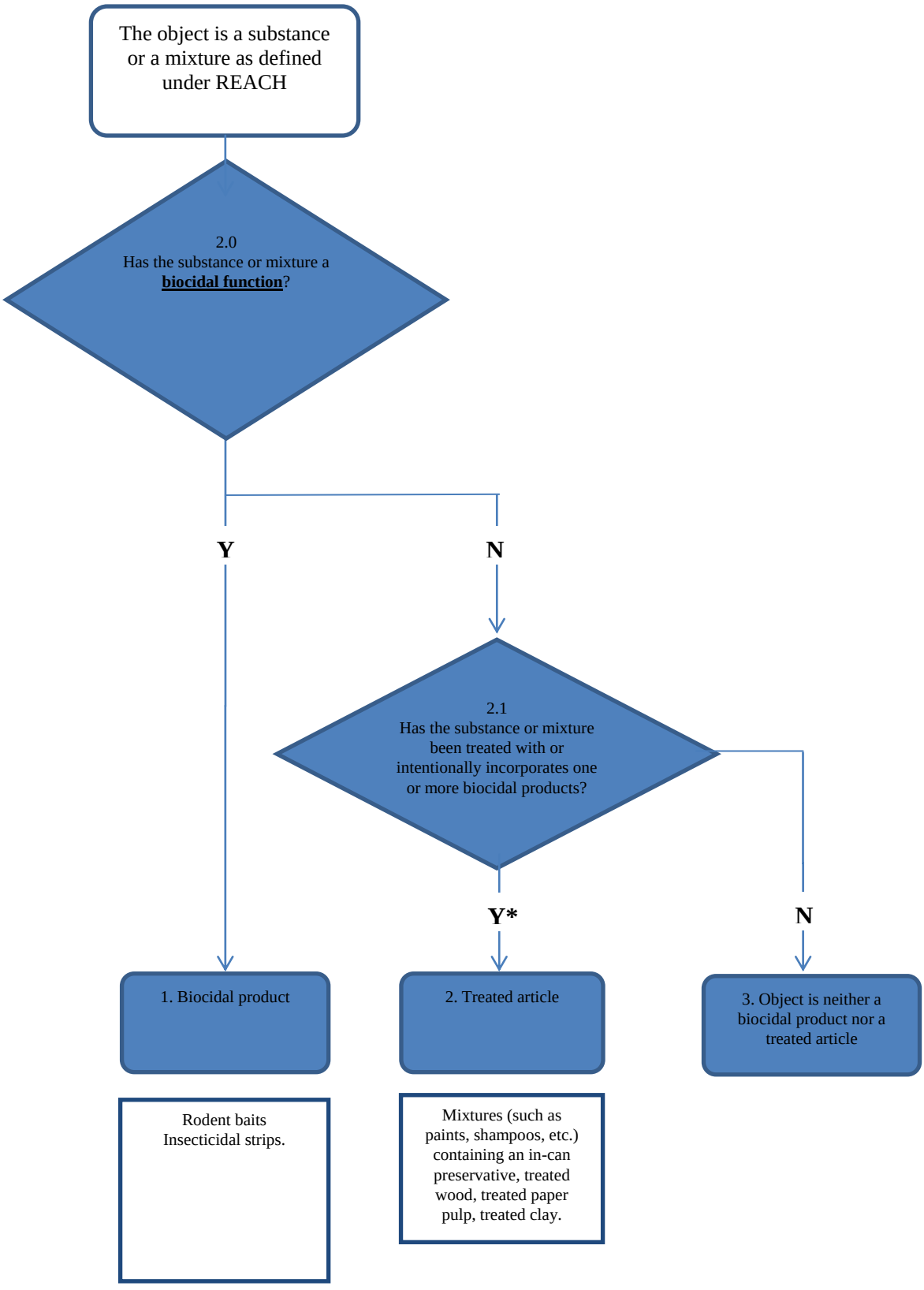
- Mixture: means a mixture or solution composed of two or more substances;

- 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.

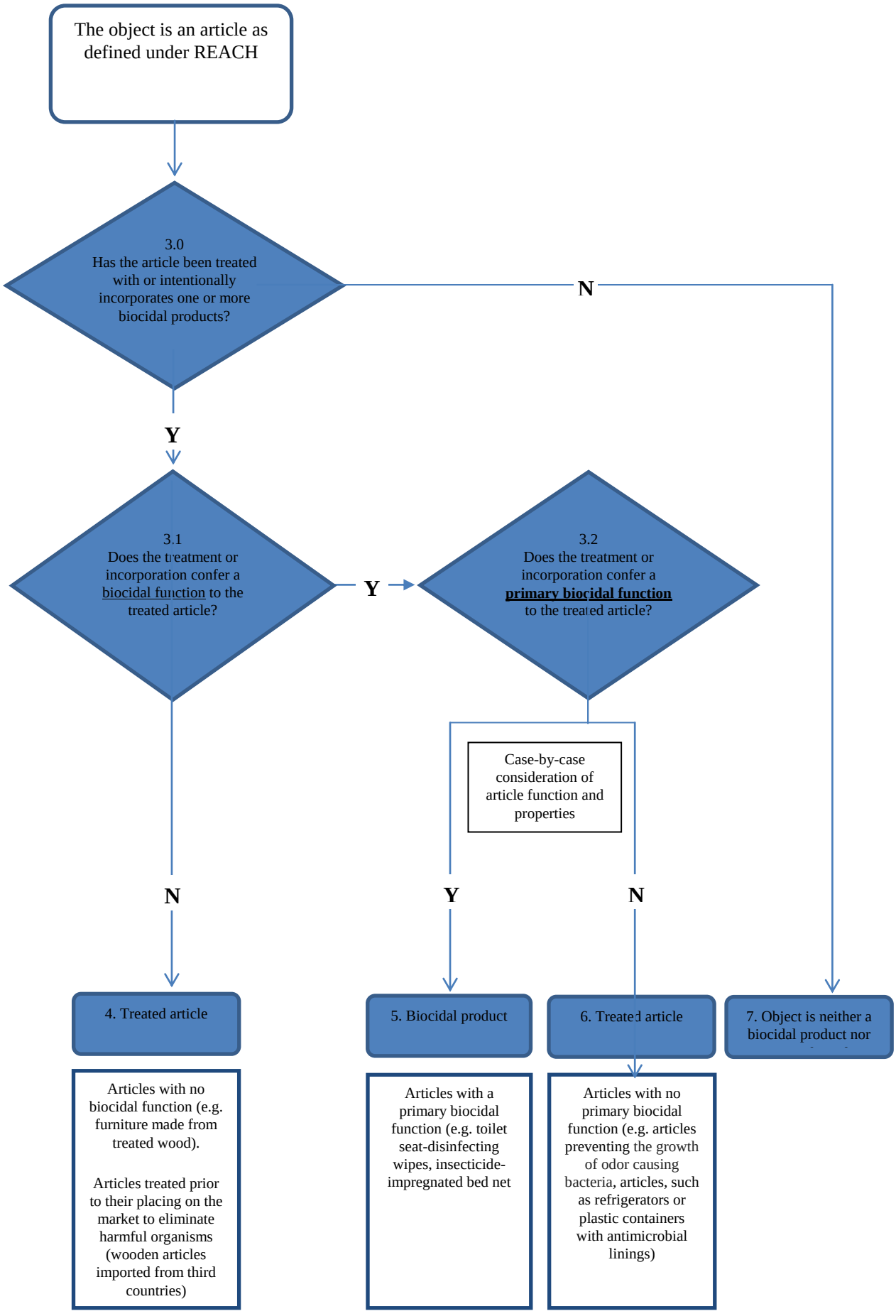


*** ECHA guidance on requirements for substances in articles, and in particular section 3 thereof, is available to assist stakeholders and competent authorities to decide whether an object is a substance, a mixture or an article.**

[2] 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.



*** 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
3.0
Has the article been treated with or intentionally incorporates one or more biocidal products?
N
Y
3.1
Does the treatment or incorporation confer a biocidal function to the treated article?
Y
3.2
Does the treatment or incorporation confer a primary biocidal function to the treated article?
Case-by-case consideration of article function and properties
N
Y
N
4. Treated article
5. Biocidal product
6. Treated article
7. Object is neither a biocidal product nor
Articles with no biocidal function (e.g. furniture made from treated wood).
Articles treated prior to their placing on the market to eliminate harmful organisms (wooden articles imported from third countries)
Articles with a primary biocidal function (e.g. toilet seat-disinfecting wipes, insecticide-impregnated bed net
Articles with no primary biocidal function (e.g. articles preventing the growth of odor causing bacteria, articles, such as refrigerators or plastic containers with antimicrobial linings)

Active substances

17. Question: In Article 58(2) of BPR, what does 'all active substances contained in the biocidal products' mean?

    Proposed Answer: This is to be understood to include the active substances contributing to the biocidal function(s) of the biocidal product(s) incorporated into the treated articles as well as active substances, which do not contribute to these biocidal functions.

    In-can preservatives contained in a biocidal product of another product-type are typical examples of active substances, which do not contribute to the biocidal function of the biocidal product.

    This means that all active substances contained in the biocidal products with which the article has been treated will have to be approved for the purpose for which they are used. Thus, in the example of wood treated with a wood preservative containing an in-can preservative, both the wood preservative and the in-can preservative will have to be approved.

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

    Proposed Answer: This is to be understood to include all active substances which contribute to the biocidal properties of the treated article targeted by the claim, or for which the conditions of approval so require.

    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 and contained 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.[3]

19. Question: If an article 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 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?

    Proposed answer: No, Article 58 of BPR only applies where the article was treated with a biocidal product. This means that the product (and hence the active substance) must have been applied with the intention of exerting a biocidal property or function.

[3] This interpretation could be seen as being at odds with the previous one. However, the objectives of 58(2) and 58(3) are not the same: In the first case the objective is to protect public and animal health and the environment from non-approved active substances, which thus justifies a wider interpretation. However, in the second case, the objective is to allow consumers to make informed choices when a claim is made about the biocidal properties of a treated article. In addition, it would be disproportionate to require information about active substances other than those that triggered the labelling requirement in the first place, i.e. those which contribute to the biocidal properties or for which the conditions of approval so require.

However, in case of controls by competent authorities, the burden of the proof will be placed on the person placing the treated article on the market to demonstrate that the substance, if it is not approved in the EU for the relevant product-type and use, was not incorporated for its biocidal activity but for other specific purposes.

20. Question: What if none of the active substances contained in the biocidal product used to treat the article remain in the treated article?

    Proposed answer: Whether the active substances contained in the biocidal product used to treat the article remain or not in the treated article is not relevant. Article 58 applies as soon as an article is treated with or intentionally incorporates a biocidal product, whether the active substance contained in that biocidal product eventually remains in the treated article or not.

    The only exception concerns goods stored or contained in a premise or, respectively, container, which was fumigated or disinfected, on the condition that no residues would be expected to remain after such treatment (see also exemption).

ACTIVE SUBSTANCE APPROVAL

Relevant product-type and use

21. 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 indicating the particular use in the approval. For example, for PT 9 (fibre, leather, rubber and polymerised materials preservatives), the following use conditions could be included in the approval:

    - All, except certain uses identified as problematic in the assessment,
    - For use in textile,
    - For use in cotton/wool/silk/polyester textile,
    - For use in textile used for clothes/carpeting/upholstered furnishings/window shades/towels/covering for tables, beds, and other flat surfaces, etc.

    The more specific, the higher the impact; the less specific, the more difficult it might be to consider the specific risks.

    Proposed Answer: The assessment of an active substance is done on the basis of a representative product, which 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 made in the active substance approval.

    With the introduction of provisions for treated articles in the BPR, the basic principle that AS approval is based on one representative biocidal product has not been changed. It

is not practicable to assess all possible uses in treated articles at the time of active substance approval, as (i) such uses can be diverse, and (ii) there is no obligation for the applicant for an active substance to provide relevant information.

Given the practical limitations of a specific listing of relevant uses in the active substance approval, they can only be included where there is already a well-established and codified practice, such as for wood preservatives.

For other product-types, the approval of an active substance would generally also cover the use in treated articles, unless specific reasons for concerns exist that such uses could pose a risk which would justify restricting the approval and excluding the use in all or particular treated articles. Such restrictions would be considered if the active substance meets one of the exclusion criteria listed in article 5(1) :

A restriction could also be considered if there are reasons for concern linked to the nature of the critical effect, which in combination with certain foreseeable use pattern could pose a risk to the user of a treated article

In conclusion, relevant use and product-type" should be interpreted as meaning any use covered by the relevant product-type, with the exception of uses explicitly excluded in the conditions of approval.

Conditions or restrictions of the approval

22. Question: How to apply the conditions or restrictions of the approval?

Proposed Answer: The assessment of an active substance is done on the basis of a representative product, which implies that not of all possible uses of an active substance are considered at the time of approval of an active substance.

The current practice is to generally open the scope of the approval to all possible uses of an active substance within the approved product-type, unless an unacceptable risk has been identified for human or animal health, or the environment. In such cases, restrictions will have been introduced, which shall also apply to treated articles. Moreover, the use in all or specific treated articles may be excluded in the active substance approval if concerns are identified during the assessment using the criteria listed above.

In many cases, a risk or concern identified at the time of the approval are due to a narrow dataset or it is possible to mitigate the risk by appropriate means. In such cases, approval of a certain use usually requires the submission of additional data at the product authorisation stage to bridge the knowledge gap or to demonstrate that the use is acceptable when certain risk mitigation measures are applied. Condition and restrictions of the approval thus imply that the substance cannot be used in this way for the treatment of articles, and articles treated in this way must not be placed on the market, until the requested data have been reviewed.

It will not be possible to amend the conditions of active substance approval every time additional data are submitted at product authorisation providing evidence that the risk initially identified can be mitigated. Thus, as soon as a product is authorised and the use

is found acceptable, the active substance could then be used in this way for the treatment of articles, and articles treated in this way may be placed on the market.

For treated articles manufactured in non-EU countries and intended to be imported into the EU, manufacturers/importers can lift restrictions of the approval of an active substance by making an application for an amendment of the approval in accordance to article 7, accompanied by relevant data for the intended use.

23. 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.

Proposed 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 disinfecting properties, 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 disinfecting properties, whilst product-type 9 covers products used for the preservation of fibres.

SCOPE

Complex articles

24. Question: Do the requirements for treated articles cover treatments only of the finished article, or treatments of components that were treated further back in the supply chain? If so, how far back in the supply chain do possible treatments have to be identified? For example, a table is manufactured outside the EU from composite wood, and the wood is bound with glue containing a 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 fungicidal properties (and no other part of the TV was treated). Does the active substance in the fungicide have to be approved?

    Proposed answer: BPR defines a treated article as 'any substance, mixture or article which has been treated with, or intentionally incorporates one or more biocidal products'. This is to be understood as covering both treatment of the article itself as well as the treatment of any of its components further back in the supply chain. Thus complex articles such as cars, ships, planes are subject to the provisions of Article 58. It is however recognised that such earlier treatments of components might be difficult to identify, especially for complex articles. Practical enforcement is therefore likely to concentrate on articles where man or the environment can be exposed to the treated components.

25. Question: What if only a small part of an article has been treated or incorporates a biocidal product?

    Proposed answer: BPR does not make such a distinction. Thus, the provisions of Article 58 apply, even if only a small part of an article has been treated with or incorporates a biocidal product.

26. 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?

    Proposed answer: In REACH, the presence of an identified "substance of very high concern" constituting ≥0.1% by weight of a given article triggers duties for the supplier to communicate information down the supply chain (REACH Article 33). However, there is no support in BPR for using a trigger value of 0.1%. The purpose of the rules in BPR relating to treated articles is to make sure that non-approved biocidal active substances are not present in Europe at all, and the percentage of a substance in relation to a treated article is irrelevant for this purpose.

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.

Proposed answer: No, a treated article is an article that is "treated with, or intentionally incorporates, a biocidal product". In this case the biocide is not used to treat the article, and is not intentionally incorporated into the article. Therefore it does not have to be approved when the article is placed on the EU market.

Product-type of a treated article considered as biocidal product

28. Question: To which product-type would a treated article considered as a biocidal product belong?

    Proposed Answer: This would be a case-by-case decision depending on the nature of the primary biocidal function of the article as well as on the claims made.

    However, as in most cases the function will be the result of the incorporation of a biocidal product belonging to product-type 2, 18 or 19 and one would expect the treated article to belong to:

    Product-type 1, if a biocidal product belonging to product-type 2 was incorporated in the article, and the article is to be in contact with human skin or scalp;

    Product-type 2, if a biocidal product belonging to product-type 2 was incorporated in the article and the article is not to be in contact with human skin or scalp;

    Product-type 18, if a biocidal product belonging to product-type 18 was incorporated in the article;

    Product-type 19, if a biocidal product belonging to product-type 19 was incorporated in the article.

    In cases where the treated article would fall under a different PT than the biocidal product it has been treated with or it incorporates, the active substance will also need to be approved for the PT of the treated article.

Exemption

29. Question: What is the scope of the exemption foreseen in Article 58(1) of BPR?

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

    This provision can be relevant 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 and placed on the EU market to prevent the transmission of organisms presenting a risk to animal or human health.

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

    Proposed Answer: The exemption covers all goods that were in the premises or containers.

31. Question: When can it be expected that no residues remain from such treatments?

Proposed Answer: It is the responsibility of the importer to assess whether residues can be expected to remain from such treatment. If residues are remaining, then the provisions of Article 58 will apply in full, if not, the exemption is applicable.

If the importer 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 will apply in full.

EU versus US approach

32. Question: How does the US regulate treated articles?

Proposed answer: The US Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires the registration of any substance intended to prevent, destroy, repel, or mitigate pests, and of any article treated with such a substance. However, the Code of Federal Regulations prescribes the conditions under which an exemption from registration is allowed for treated articles or substances.

Exemptions are only allowed for an article or a mixture treated with or containing a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insects or fungus infestation), if the pesticide is registered for such use.

Claims for treated articles or substances which can be made while still benefitting from the exemption are limited to the following statement, "This product contains a preservative (e.g., fungicide or insecticide) built-in or applied as a coating only to protect the product."

The treated articles exemption is available only for pesticides used for the protection of the product, and not for public health uses.

LABELLING OF TREATED ARTICLES

Claim regarding the biocidal properties of a treated article

33. Question: What is a claim regarding a biocidal property?

Proposed 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 efficacy or action against unwanted organisms. In this case, a claim thus refers to a biocidal function of the treated article.

- or 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.

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 substantiated claim).

34. 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?

Proposed 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 settlement 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: Working or cutting fluid preservatives	Contains a preservative to control microbial deterioration 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 control insects. Contains an insecticide. Contains an acaricide.
Product-type 19: Repellents and attractants.	Contains an insect repellent.

Substantiated claims

35. 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?

    Proposed 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 need to substantiate any claim made follows also from the provisions of Directive 2001/95 on the General Safety of Products.

Public health claims

36. Question: What is a public health claim?

    Proposed answer: A public health claim is a statement that the treated article is expected to provide certain benefits against organisms of public health relevance if used as indicated or implied by the person placing the article on the market.

Public health claims 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, as well more unspecific claims such as the following:

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

Public health related claims must deserve a greater level of scrutiny because of their potential impact on public health. Thus, when such claims are made on a treated article, it should be considered whether this would confer to the treated article a primary biocidal function.

More than one active substance

37. Question: If the 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?

    Proposed Answer: When an 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 so require (see also section 'Active substances').

Nanomaterial

38. 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?

    Proposed 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

39. 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?

    Proposed 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 in incorporated in a new product, which itself will then meet the definition of a treated article, the person responsible for placing on the market this product needs to comply to the labelling provisions of article 58(3).

Location of the claim

40. Question: Where does a biocidal claim have to be made for labelling to be required? For example, an article is marketed without mention of biocidal properties, but it is mentioned in the technical documentation accompanying an article that it has been treated with a biocide for a purpose other than just preservation of the article itself.

    Proposed answer: BPR does not specify where a claim has to be made. 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

41. 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?

    Proposed answer: The decision where to place the label will be a case-by-case decision depending on the individual features of the article in question. Article 58(6) implies that whenever possible, the label should be affixed to the 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 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

42. 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?

    Proposed answer: This is the responsibility of the person placing the treated article on the market to see, in view of the possible risks that the treated article may pose to human or animal health or the environment, 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

43. Question: Do intermediates or raw materials treated with or incorporating a biocidal product need to be labelled?

    Proposed answer: If these intermediate or raw materials meet the definition of a treated article, the provisions of the entire Article 58 will apply to them if they are 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.

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?

    Proposed Answer: This is for the person placing the treated article on the market and relying on sector-specific legislation to prove, in case of control, that the labelling requirements for treated articles are addressed through the sector-specific legislation.

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?

    Proposed 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?

    Proposed Answer: There is no requirement to indicate an expiration date on the treated article. The manufacturer of the article can however do it – at its own will – if they deem it useful.

Deadline for labelling of treated articles

47. Question: Art 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)?

    Proposed answer: The BPR does indeed not foresee transitional measures for the labelling of treated articles. This means that all treated articles on the market by 1 September 2013 will have to comply with the labelling rules set in article 58(3) by this date.

    It has to 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.

Antibacterial claim

48. Question: Is it acceptable to indicate 'antibacterial' on the label of a treated article?

Proposed Answer: Such a claim regards the biocidal function of the treated article and could constitute a public health related claim. It would thus need to be assessed, on a case-by-case basis and taking into account the properties and functions of the treated article, whether the treated article could be considered as having a primary biocidal function, which would mean that the treated article would be regarded as a biocidal product and would have to be authorised as such.

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.

TRANSITIONAL ARRANGEMENTS FOR TREATED ARTICLES

Please note that the answers in this section are based on the current text of the BPR and might be subject to revision in the event changes that are made to Article 94 of BPR as intended.

49. Question: What consequences does the differentiation between existing and new active substances have for treated articles?

    Proposed Answer: The differentiation between existing and new active substances should have a critical consequence. Articles already available on the market on 1 September 2013 that are treated with a new active substance before it has been approved for the relevant product-type, can no longer be placed on the market after 1 September 2016 unless an application for the approval of that active substance product-type combination was submitted before 1 September 2016.

    To the contrary, articles already available on the market on 1 September 2013 that are treated with an existing active substance which is still under assessment on 1 September 2016 in the review programme for existing active substances for the relevant product-type could be placed on the market pending a decision on the approval of that active substance product-type combination.

    For the purpose of treated articles, new active substance product-type combinations for which applications for approval will have been submitted by 1 September 2016 could be assimilated with existing active substances product-type combinations under assessment in the review programme.

Treated articles containing existing active substances

50. Question: An article, already placed on the market on 1 September 2013, is treated with a biocide containing an active substance that is currently supported 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?

    Proposed answer: Yes, Article 94 of BPR says that if the article is already on the market on 1 September 2013, it can continue to be placed on the market if the application for approval is submitted by 1 September 2016. In this case the application for approval has already been submitted (so it has been submitted by 1 September 2016). So the article can remain on the market.

51. Question: An article treated with an existing active substance, which was subject to a non-inclusion decision, is marketed. As far as one knows, no new application will be made to support the active substance. When does the article have to be removed from the market?

    Proposed answer: Article 94 of BPR says that in case of a decision not to approve an active substance for the relevant product type, treated articles have to come off the market 180 days after the decision or 1 September 2016, whichever is the later. In this case the non-inclusion decision has already been issued, so the article must be removed from the market on 1 September 2016.

Treated articles containing new active substances

52. Question: What if a new article is placed on the market with a new active substance? Can it be placed on the market during the review of the new active substance, or does it have to wait with marketing until the substance is approved.

    Proposed Answer: After 1 September 2013, a new article with a new active substance will only be allowed to be placed on the market after that substance has been approved.

53. Question: What if an importer wants to import a treated article containing an active substance which is approved for another product type than the one in which it was used to treat the article? Can the article be marketed while the importer defends the approval of the substance?

    Proposed Answer: An application must be submitted with a view to approve the substance for the new product-type. If the article was already on the market on 1 September 2013, then the transitional measures of Article 94 apply. If not, the new product-type must be approved before the article can be placed on the EU market.

54. Question: An article, already placed on the market on 1 September 2013, is treated with an active substance that is not currently in the review programme. The treated article manufacturer or someone else applies for approval of that active before 1 September 2016. Can the article be kept on the market?

    Proposed answer: The article is already on the market on 1 September 2013, so it can remain on the market until 1 September 2016. If an application for approval is submitted by that date, the article can remain on the market until a decision is taken on whether to approve the active substance. In case of a decision not to approve, the article must come off the market within 180 days.

55. Question: An article treated with an active substance that is not currently in the review programme because it was never identified or notified (it has never been used in biocidal products in the EU) is marketed. As far as one knows, no-one is going to support the active substance now. When does the article have to be removed from the market?

    Proposed answer: Article 94 allows the article to remain on the market until 1 September 2016. Because the active substance was never included in the review programme there will be no non-inclusion decision. Therefore, if no application is made for approval, it must be removed from the market on 1 September 2016 according to Article 94(2).

Treated articles already available on the EU market on 1 September 2013

56. Question: Some changes are made to the design of a treated article already available on the EU market on 1 September 2013, but the article will continue to be treated with or to intentionally incorporate the same biocidal product. Would that be allowed?

    Proposed answer: Provided that the changes made do not affect the use and foreseeable exposure and risks from the biocidal product incorporated into the treated article, limited changes to the design of an existing treated article should be permissible (e.g. change of colour, shape, or size).

57. Question: A new article is introduced in a range of treated articles article already available on the EU market on 1 September 2013, but this article will be treated with or will intentionally incorporate the same biocidal product. Would that be allowed?

    Proposed answer: Provided that the new articles are treated with or incorporate the same biocidal product and that the use and foreseeable exposure and risks from the biocidal product incorporated into the article remain the same, addition of a treated article to a range of existing treated articles should be permissible.

MISCELLANEOUS

Link with Article 95

58. Question: does Article 95 of BPR apply to treated articles, i.e. can an article only be treated with a biocidal product containing an active substance where the supplier has submitted a dossier or a letter of access to ECHA?

    Proposed answer: No, the requirements on alternative suppliers in Article 95 do not apply to substances used only in treated articles governed by Article 58 of BPR – only to substances placed on the EU market in biocidal products, or with the intention of being used in biocidal products.

Packaging

59. Question: For the purpose of the provisions on treated articles, is the packaging of an article regarded as part of the article itself?

    Proposed answer: According to the REACH[4], packaging does not become part of the packaged article, but remains a separate article.

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

ANNEXES

Annex I

Extracts from Regulation (EU) No 528/2012

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)[5] that are not biocidal products within the meaning of Article 3(1)(a)[6]. 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 that treated article shall ensure that

   – 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

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[5] l) treated article" means
any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products;

[6] 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 are not themselves biocidal products under the first subparagraph 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 produc*t.*

– where, in relation to the active substance(s) concerned, having particular regard to the possibility of contact with humans or the release to the environment, the conditions associated with the approval of the active substance(s) so require,

the label provides 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 and without prejudice to Article 89, treated articles that were available on the market on 1 September 2013 may, until the date of a decision concerning the approval for the relevant product type of the active substance(s) contained in the biocidal products with which the treated articles were treated or which they incorporate, continue to be placed on the market if the

application for the approval of the active substance(s) for the relevant product type is submitted at the latest by 1 September 2016.

2. In the case of a decision not to approve an active substance for the relevant product type, treated articles which were treated with, or which incorporate, biocidal product(s) containing that active substance shall no longer be placed on the market 180 days after such a decision or as of 1 September 2016, whichever is the later, unless an application for the approval has been submitted in accordance with paragraph 1.

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 impregnate 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.

[…]