A·I·S·E

International Association for Soaps,
Detergents and Maintenance Products

BPR Requirements for Treated Articles

A.I.S.E. Biocides WG

First revision - December 2017

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Outline

1. Scope: treated articles versus biocidal products
2. BPR Article 58 (2) and transitional measures for treated articles (BPR Article 94)
3. BPR Article 95 requirements
4. Labelling of treated articles
5. Provisions for treated articles in active substances approval decisions

1. Scope: treated articles versus biocidal products

Definitions

- Definition of a treated article:
  - BPR Article 3: *"any substance, mixture or article which has been **treated with**, or intentionally **incorporates**, one or more **biocidal products**"*
  - *"A treated article that has a primary biocidal function shall be considered a biocidal product"*

Example:
A disinfecting wipe for surfaces (with a biocidal claim e.g. kills bacteria) is a treated article with primary biocidal function
= biocidal product

Important remark on the definition:
A treated article is treated with (or intentionally incorporates) a biocidal product, not with an active substance

Commission guidance on treated articles

- FAQ on Treated Articles (CA-Sept13-Doc.5.1.e Revision 1, Dec. 2014)
  - Examples related to detergents:
    - Treated Article: “Mixtures like paints, glues, inks, detergents, etc. containing an in-can preservative”
    - Not a treated article: “Paint, detergents, etc. containing an additive, and that additive had an in-can preservative added in order to protect it during storage, where this preservative has no further preserving function in the final product”

Example:
An acidic cleaner is formulated with a surfactant B that is supplied as a mix ‘surfactant B + in-can preservative Z’

In-can preservative Z has no preserving function in the final acidic cleaner, because it is inefficient at low pH. The acidic cleaner does not need to be preserved due to its very low pH

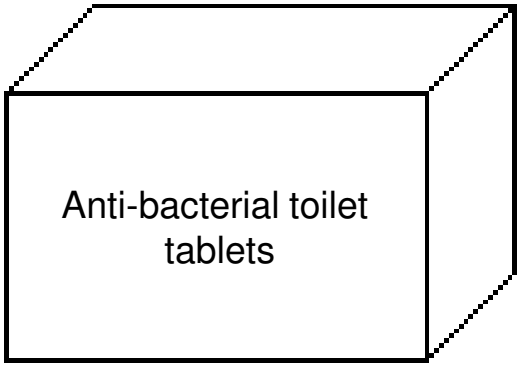
*=> **NOT** a treated article*

‘Mix B’:
Surfactant B +
in-can
preservative Z

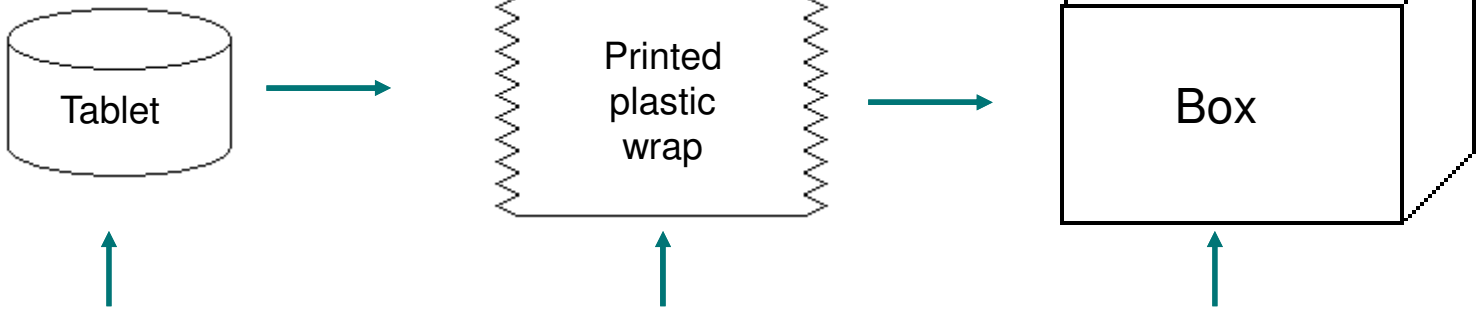
Acidic cleaner:
- Acid A
- Surfactant B
- Surfactant C
- Perfume D
- water

(In-can
preservative Z)

Examples



Anti-bacterial toilet tablets composed of:



Biocidal claim
PT2 Active
= Biocidal product

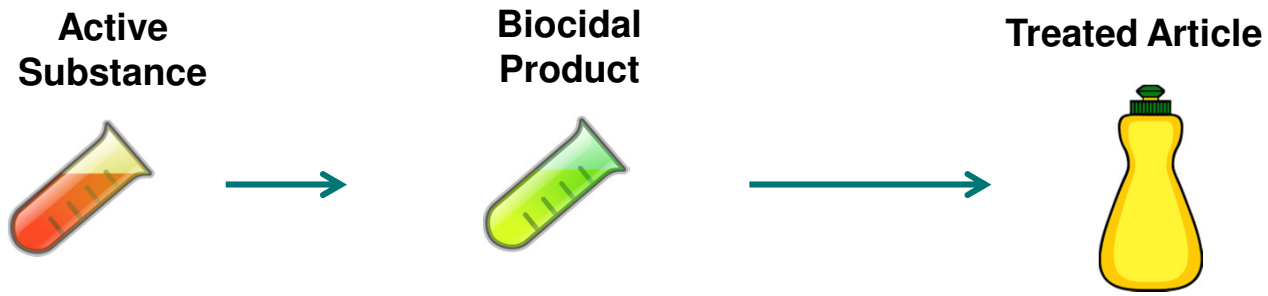
Uses ink that contains preservative to protect ink before printing
= Not a Treated Article

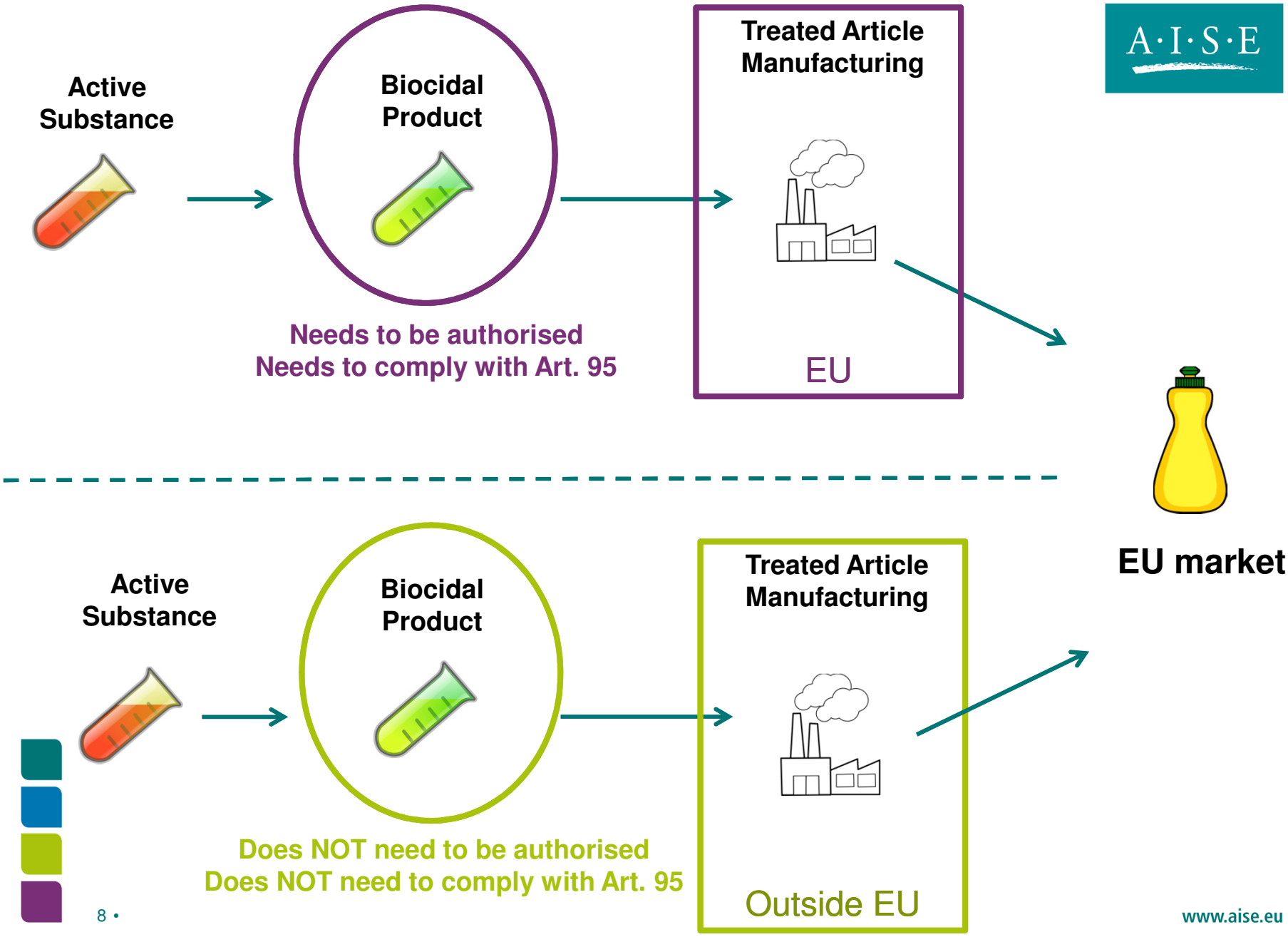
Contains preservative to stop box going mouldy in damp bathroom.
No claim, but intended activity.
= Treated Article

Important remarks

- Definition of a treated article: *"any substance, mixture or article which has been **treated with**, or intentionally **incorporates**, one or more **biocidal products**"*

A treated article is treated with (or intentionally incorporates) a biocidal product, NOT with an active substance




Active Substance
Biocidal Product
Treated Article Manufacturing
Needs to be authorised
Needs to comply with Art. 95
EU
EU market
Active Substance
Biocidal Product
Treated Article Manufacturing
Does NOT need to be authorised
Does NOT need to comply with Art. 95
Outside EU

Further remarks

- When the treated article is imported from outside EU, does the biocidal product used to treat the article have to be authorised in EU?

  ⇨ No, if the treated article is produced outside EU, the biocidal product does not have to be authorised. So for instance in the case of a preserved liquid detergent manufactured in China, the in-can preservative (PT6 product) used does not have to be authorised in EU. However the active substance(s) contained in the preservative has(ve) to be approved, under review or on Annex I (see slide 12)

- A preserved liquid detergent is manufactured in France. Does the in-can preservative (PT6 biocidal product) have to be authorised in France? Can the detergent be sold in other EU countries?

  ⇨ Yes, the in-can preservative has to be authorised in France, otherwise it cannot be made available on the market or used in France (refer to BPR Art. 17)

  ⇨ Yes, the detergent (= the treated article) can be sold in other EU countries, since it is subject only to BPR Art. 58 requirements for placing on the market of treated article (unless the treated article is considered as a biocidal product)

2. BPR Article 58 (2) and transitional measures for treated articles (BPR Article 94)

BPR Art. 58 (2) obligation

- BPR Art. 58 (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."

Remark: The list drawn up in accordance with Art. 9(2) is the list of approved active substances

Imported treated articles

- Do treated articles imported from outside the EU need to comply with BPR?

⇨ Yes, in addition to more general regulations like REACH, CLP and Detergent, the BPR also applies to imported products that have been manufactured and treated with biocide(s) outside the EU. All active substances in treated articles have to be approved, under review or on Annex I. Imported treated articles are no exception to this.

BPR Art. 58 (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."

BPR Article 94

- **From 1 Sept 2013: the active substance contained in the biocidal product used to treat the article has to be either already approved, or under evaluation in the Review Program for the relevant PT, or in BPR annex I**

- **If the active substance is not in Review Program:**

  => Possibility to submit an application for AS / PT until 1 Sept 2016

  => Possible to place the TA on the market until 1 Mar 2017

⇨ After 1 March 2017: AS has to be approved or under evaluation or in BPR Annex I

- **Non-approval decision:** After 1 Sept 2016, if the active substance is not approved under the review program

  => 180 days after that non-approval decision to stop placing on the market

- **Where several active substances are concerned (Art. 94.1 (b))**

  => May be placed on the market until the date of approval of the last active substance contained in the biocidal product

  => Subject to relevant product type

Refer also to Commission FAQ on Treated Articles (CA-Sept13-Doc.5.1.e Revision 1, December 2014), section "Transitional arrangements for Treated Articles"

BPR Article 94 - Examples

- Example 1:

  Company A currently uses an in-can preservative based on ‘active substance A’. ‘active substance A’ is not supported under BPR (not in the EU approval process)

  On 1 Sept 2016, no application dossier for ‘active substance A’ for the relevant PT has been submitted

  ⇨ Company A can place the laundry liquid detergent on the market until 1 March 2017

- Example 2:

  Company A currently uses an in-can preservative based on ‘active substance B’ to preserve a laundry liquid detergent

  On 1 Dec. 2016 the ‘active substance B’ receives a non-approval decision at EU level

  ⇨ Company A has 180 days to stop placing the laundry liquid detergent on the market

- Example 3:

  Company A currently uses an in-can preservative based on ‘active substance C’ and ‘active substance D’ to preserve a laundry liquid detergent.

  Dates for approval for ‘active substance C’ and ‘active substance D’ for PT6 are 1 May 2016 and 1 April 2017 respectively

  ⇨ Company A may place the laundry liquid detergent on the market under transitional measures acc. to Art. 94 until 1 April 2017, based on ‘active substance D’ approval date

Remark

Important :
*The deadlines for treated articles are referring to '**placing on the market**' (i.e. making available on the market for the 1st time); as such the subsequent supply and use are not affected*

Refer to Commission FAQ on Treated Articles (CA-Sept13-Doc.5.1.e Revision 1, December 2014), Q&A # 51:

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.

3. BPR Article 95 requirements

Does Article 95 apply to treated articles?

⇨ No, not directly. Article 95 applies only to biocidal products. Only authorised biocidal products may be used in treated articles, if the treated article is produced in the EU. For a biocidal product to be authorised, it needs to comply with the requirements of Article 95.

*If a detergent is manufactured in the EU , the biocidal product (= the in-can preservative) used to treat the detergent is placed on the EU market, so needs to comply with Art. 95 * - refer to the FAQ from the COM on Treated Articles CA-Sept13-Doc.5.1.e Rev1, Dec 2014 (see next slide)*

** As for any biocidal product, the active substance supplier or the product supplier must be on Art. 95 list (at least one party in the supply chain must be on Art. 95 list or lead back to a source on Art. 95 list)*

Does Article 95 apply to treated articles?

FAQ from the COM on Treated Articles CA-Sept13-Doc.5.1.e Rev1, Dec 2014:

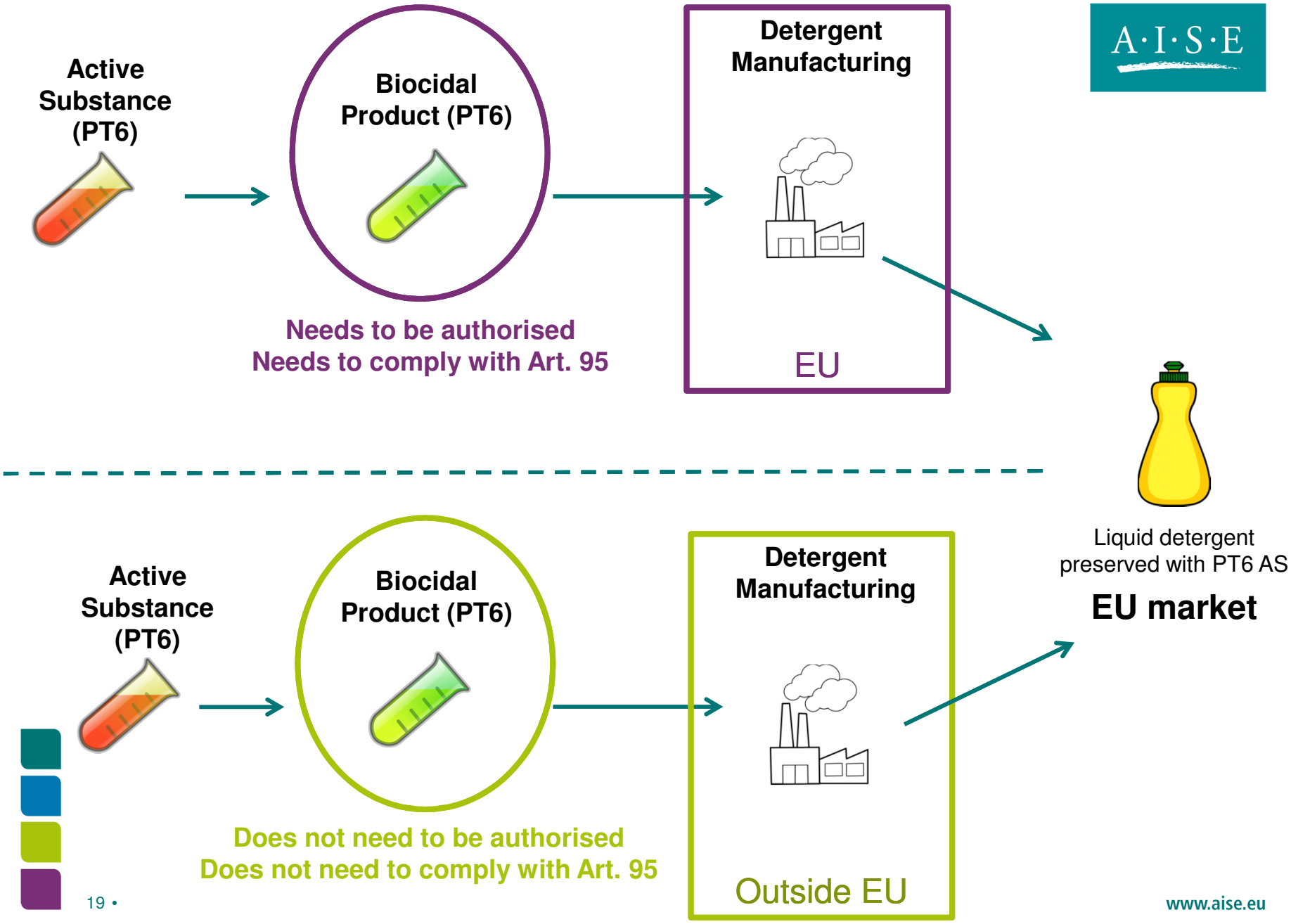
Link with Article 95

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.


Active Substance (PT6)
Biocidal Product (PT6)
Needs to be authorised
Needs to comply with Art. 95
Detergent Manufacturing
EU
Active Substance (PT6)
Biocidal Product (PT6)
Does not need to be authorised
Does not need to comply with Art. 95
Detergent Manufacturing
Outside EU
Liquid detergent preserved with PT6 AS
EU market

4. Labelling of treated articles

BPR Article 58 (3)

- Treated articles have to be labelled according to Art. 58 (3) **only if**:
  - A claim is made about the biocidal properties of the treated article

    e.g. : biocide is added intentionally, with claim and/or market positioning regarding its biocidal properties gained from using biocides (e.g. mould resistant polish)
  - When the conditions associated with the approval of the active substance concerned require specific labelling provisions

The majority of 'regular/ normal' detergents & cleaning products are not subject to this requirement

Commission note CA-May15-Doc.6.1-Final ‘labelling of treated articles’

- For treated articles for which the **active substance concerned is skin sensitiser Cat 1 or Cat 1A, provisions of BPR Art. 58(3) should apply**

- This specific labelling provision will be imposed through the substance approval decision

BPR Art. 58 (3):

“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;

(d) the name of all nanomaterials contained in the biocidal products, followed by the word ‘nano’ in brackets;

(e) 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.

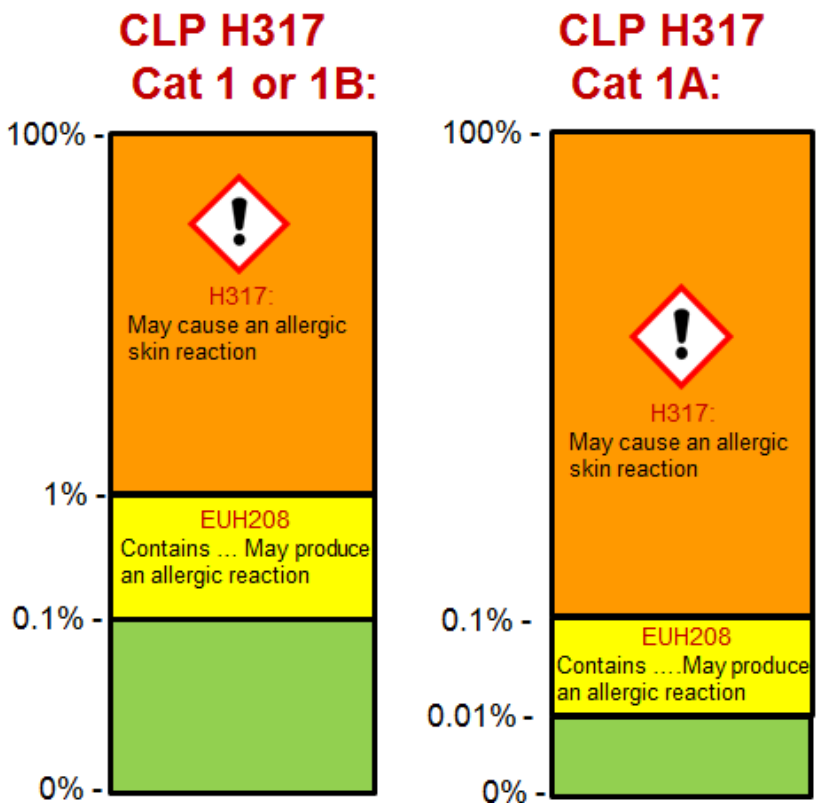
This paragraph shall not apply where at least equivalent labelling requirements already exist under sector-specific legislation for biocidal products in treated articles to meet information requirements concerning those active substances.”

Guidance on how to address BPR Art. 58(3) requirements in the case of skin sensitisation

BPR Article 58 (3) **The label […] shall provide the following information:**	How to address **detergents, cleaning & maintenance products**
(a) a statement that the treated article incorporates biocidal products	**Include 'contains preservative' in the ingredient labelling**
(b) where substantiated, the biocidal property attributed to the treated article	**Include 'contains preservative' in the ingredient labelling** (NB: the treated article is preserved so it has a biocidal property)
(c) without prejudice to Article 24 of Regulation (EC) No 1272/2008, the name of all active substances contained in the biocidal products	**Already covered by the Detergent Regulation labelling requirements: name of the in-can preservative(s) are listed on label (INCI name) ***
(d) the name of all nanomaterials contained in the biocidal products, followed by the word 'nano' in brackets	A priori irrelevant (PT6 biocidal products are very unlikely to contain nanomaterials)
(e) 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.	**As appropriate (left to companies to decide)** **As a general principle, A.I.S.E. believes that CLP is appropriate for informing and warning users about potential hazards and related precautions to be taken** (see next slide case of skin sensitisation)

*** For products not subject to the Detergent Regulation labelling requirements (e.g. PC&H products), then the name of all active substances contained in the biocidal products need to be added on the label**

CLP requirements with regard to skin sensitisers in mixtures:



The figure above illustrates the case of Generic Concentration Limit, in case of Specific Concentration Limit (SCL), EUH208 applies at 1/10 of the SCL

Example of labelling

Mop head with natural fibres

- Mop head treated with preservative “X” to prevent spoilage by odour-causing mould and bacteria
- Claim on biocidal property is made: ‘germ resistant mop’
- No primary biocidal function = Treated Article

Treated Article labelling - implementation of Article 58.3:

BPR Art. 58.3 (a), (b) & (c) → Contains preservative (“X”)

BPR Art. 58.3 (e) → + any relevant instructions for use & any precautions to be taken, considered by the manufacturer

Example of “non-labelling”

Paint containing an in-can preservative

- Product contains preservative to prevent spoilage in storage
- No primary biocidal function = Treated Article
- No biocidal claims nor claims on the biocidal property gained are made

Since no biocidal claims nor claims on the biocidal property gained are made on product, the treated article label is not required unless required by the conditions of the active substance approval.

Example with skin sensitiser

Laundry detergent containing preservative which is a skin sensitiser

- Contains preservative “X” to prevent spoilage of liquid from microbial growth
- Preservative “X” is a known skin sensitiser Cat 1A (no SCL); its concentration in the detergent is 0.15%
- No primary biocidal function = Treated Article
- No biocidal claims nor claims on the biocidal property gained are made

BPR Art. 58.3 (a), (b) & (c)
CLP (H317 statement) → **Treated Article labelling - implementation of BPR Art. 58.3 *:**

Contains preservative (“X”). May cause an allergic skin reaction.

BPR Art. 58.3 (e) → + any relevant instructions for use & any precautions to be taken, considered by the manufacturer

** Other requirements from CLP and Detergents Regulation apply. Overall classification and additional precautions will need to be considered and conform with CLP*

5. Provisions for treated articles in active substances approval decisions

Provisions for treated articles in active substances approval decisions: when to apply?

- Specific conditions related to the placing on the market of treated articles can be included in the Commission's active substance approval decisions (COM implementing regulations)

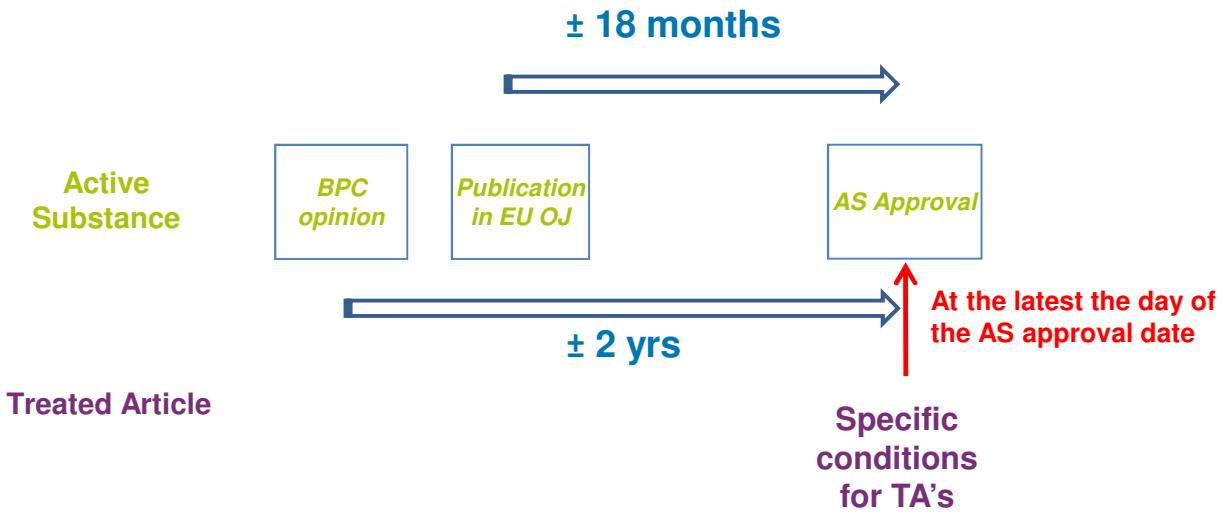
- When do the specific conditions apply?

  ⇨ **From the date of approval of the active substance***

  ⇨ **When a treated article contains multiple preservatives with different active substances, these active substances will probably have different approval dates. Companies may have to adjust their labelling multiple times.**

* Commission FAQ on Treated Articles (CA-Sept13-Doc.5.1.e Revision 1, December 2014), Q&A # 54 : *"Labelling requirements imposed by conditions in the active substance approval apply from the date of approval."*

Provisions for treated articles in active substances approval decisions: when to apply?



In practice it means +/- 18 months to implement the specific conditions related to treated articles (time between publication of the Commission's decision in OJ and date of AS approval)

Example : C(M)IT/MIT

Commission Implementing Regulation (EU) 2016/131 of 1 February 2016 approving C(M)IT/MIT (3:1) as an existing active substance for use in biocidal products for product-types 2, 4, 6, 11, 12 and 13

Specific conditions for PT6:

"The placing on the market of treated articles is subject to the following conditions:

(1) In view of the risks identified for human health, mixtures treated with or incorporating C(M)IT/MIT (3:1) and placed on the market for use by the general public shall not contain C(M)IT/MIT (3:1) at a concentration triggering classification as skin sensitiser, unless exposure can be avoided by other means than the wearing of personal protective equipment.

(2) In view of the risks identified for human health, liquid detergents treated with or incorporating C(M)IT/MIT (3:1) and placed on the market for use by professional users shall not contain C(M)IT/MIT (3:1) at a concentration triggering classification as skin sensitiser, unless exposure can be avoided by other means than the wearing of personal protective equipment.

(3) In view of the risks identified for human health, mixtures treated with or incorporating C(M)IT/MIT (3:1), other than liquid detergents, and placed on the market for use by professional users shall not contain C(M)IT/MIT (3:1) at a concentration triggering classification as skin sensitiser, unless exposure can be avoided, including by the wearing of personal protective equipment.

(4) The person responsible for the placing on the market of a treated article treated with or incorporating C(M)IT/MIT (3:1) shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012."

Date of approval of the AS: 1 July 2017

⇨ the specific conditions apply as of the 1st of July 2017

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Date of approval
C(M)IT/MIT (3:1)	IUPAC Name: Reaction mass of 5-chloro-2-methyl-2h-isothiazol-3-one and 2-methyl-2h-isothiazol-3-one (3:1) EC No: n/a CAS No: 55965-84-9	579 g/kg (theoretical calculated dry weight) The active substance is manufactured as a technical concentrate (TK) with different solvents and stabilisers.	1 July 2017