Masterbatches under the BPR - What’s new?

Dr Anna Gergely, Director, EHS Regulatory
agergely@steptoe.com
Content

- BPR: Its purpose, scope and definitions
- What is a Masterbatch and how is it regulated under the EU biocides regime?
- What is a treated article under the revised interpretation of the EU Commission?
- Impact of the scope for treated articles on the regulatory status for Masterbatches
- Remaining questions
The purpose and subject matter of the BPR

- The aim of the BPR is to regulate *those active substances and biocidal products* which are used for *intended* biocidal effects and *not* to protect the health of people and the environment in the EU from *unintended* biocidal effects.

- For these effects there are other safety/regulatory measures:
  - REACH
  - Product specific requirements
  - Specific workers’ and consumer protection legislation
  - Transport requirements etc.
## Extension of the scope of the BPR

<table>
<thead>
<tr>
<th>Active substance</th>
<th>BPD</th>
<th>BPR</th>
</tr>
</thead>
<tbody>
<tr>
<td>A substance or microorganism including a virus or a fungus having general or specific action on or against harmful organisms.</td>
<td></td>
<td>A substance or a microorganism that has an action on or against harmful organisms.</td>
</tr>
</tbody>
</table>

### Biocidal product

<table>
<thead>
<tr>
<th>Biocidal product</th>
<th>BPD</th>
<th>BPR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active substances and preparations containing one or more active substances, <strong>put up in the form in which they are supplied to the user, intended to</strong> destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.</td>
<td></td>
<td>Any substance or mixture, <strong>in the form in which it is supplied to the user</strong>, consisting of, containing or generating one or more active substances, <strong>with the intention</strong> 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.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Treated article</th>
<th>BPD</th>
<th>BPR</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td></td>
<td>Any substance, mixture or article which has been treated with, or <strong>intentionally</strong> incorporates, one or more <strong>biocidal products</strong>.</td>
</tr>
</tbody>
</table>
What is a “Masterbatch”? 

- No definition in the BPR. Proposed common definition: 

- **Masterbatch** is a pre-dispersed (solid or liquid) concentrate of additive(s), such as pigments, anti-static, UV-blockers, flame retardants, **antimicrobials (biocides)**…, allowing the processor to proportion such additives accurately to a bulk product (for example natural polymer) during the manufacturing process. Its addition is considered the industrial standard way for adding additives to the bulk product, and is typically in a form (for example granulates or pellets) making them easy to handle and to mix. Those additives are metered, or let down, into a bulk product using a predefined ratio, during the processing. (Note for Guidance CA-May15-Doc.6.2)

- Used to confer biocidal properties to the final article

- Typically marketed B2B as “interim” product

- Does a Masterbatch meet the definition of Biocidal Product under the BPR?
What is a “Treated article”?

- **New definition under the BPR:** Any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products.

- **Treated articles** were not explicitly covered by BPD - but extensive guidance on how to address individual examples in the Manual of Decisions (MoD)

- **MoD focused on the biocidal effect of treated articles, contrasting:**
  - **Internal effect:** intended to preserve the article itself, the treated article is not a biocidal product (e.g. treated paper or wood)
  - **External effect:** treated article is intended to act as a biocidal product

- **BPR introduced changes that explicitly addressed treated articles:** Article 58 deals with treated articles which are not biocidal products (no primary biocidal function)
Treated articles under the BPR

- Article 58(2) – as amended: A treated article shall not be placed on the EEA market unless all active substances contained in the biocidal product that it was treated with or incorporates are EU approved for the relevant PT and use; and the restrictions are met (exception: fumigation and disinfection of premises)
  - placed on the market means: first making available as the treated article itself
  - contained in the biocidal product: its presence in the treated article is not the requirement
  - it was treated with or incorporates means: the treated article itself and not of its component parts (see infra relevance for Complex articles)
  - EU approved for the relevant PT and use means: 0% threshold on all active substances which are not permitted pursuant to Article 58(2).

- Double intention:
  - First, the intention to use the active substance in the biocidal product is required
  - Second, the intention to use this biocidal product to treat with or incorporate into an article is required

- Article 94 – as amended: Transitional measures concerning treated articles
Is a “Masterbatch” a Biocidal Product?

- **Biocidal product** – by definition of the BPR 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.
  - If the Masterbatch in the form it is supplied to the user is not intended to have a biocidal effect; it is not a Biocidal Product

- This part of the definition has not been modified under the BPR, so the interpretation was the same under the BPD

- What is the new issue then?
The “Masterbatch” question – What is the issue?

- Masterbatches as such are not addressed by the BPR
- Legal certainty is needed for determining “whether or not a masterbatch of an active substance falls under the scope of the BPR; and if so, as a Biocidal product or a Treated article”?

Facts:
- Masterbatches are tailored for specific downstream needs – great variety in composition. If Biocidal products: large number of authorization needed
- It is the user of a Biocidal product who exploits its biocidal property
- Masterbatches are typically interim products: their potential authorisation requiring efficacy testing “in the form as supplied to the user” is meaningless

Principle requirement:

In a supply chain where an active substance is used for a biocidal intention, at least one - but only one! - biocidal product should get authorised

(postulated by the Note for Guidance CA-May15-Doc.6.2)
Proposed way - Note for Guidance CA-Sept15-Doc.6.2-rev1

- Whether the Masterbatch of an active substance itself is a Biocidal product falling under the BPR or a simple mixture, depends on the intention of its use
  - When the Masterbatch is used to manufacture a Biocidal product, it should be considered a simple mixture
  - In a Masterbatch a biocidal active substance may be present at a high concentration and exhibit biocidal activity, but if this activity is not intended to be beneficial in this form, the Masterbatch is not a Biocidal product
  - An intermediate masterbatch intended for further processing is not a Biocidal product

- **BUT:** A Masterbatch used to confer a biocidal property to mixtures or articles which are not biocidal products themselves is a Biocidal product (even if also confers other functions) – see infra

- Pursuant to Article 3(3) of the BPR – Harmonized and legally binding

- Decision on question raised by the Netherlands re polymeric binders with QUATs which themselves do not have an antimicrobial activity but are marketed for being incorporated in paints to confer to the paint the biocidal function to destroy harmful organisms. The Decision answers the questions whether
  - i) the polymeric binders with the QUATs should be considered Biocidal product
    - • ANSWER: NO: no intended biocidal function in the form
  - ii) the treated paint should be considered Biocidal product
    - • ANSWER: YES: generate an active substance with intended biocidal function
What is the issue? - Controversial interpretation

- Paints are mixtures
- Mixtures can be treated articles (if biocidal function is secondary) or biocidal products (if biocidal function is primary)
- A treated article is treated with or intentionally incorporates biocidal products
- If the polymeric binders incorporated into the paint are NOT biocidal products (as above decision); their incorporation into the paint would NOT make the paint a treated article.

How can then the paint become a biocidal product?

BECAUSE:

In a supply chain where an active substance is used for a biocidal intention, \textbf{at least one - but only one!} - biocidal product should get authorised
What is the issue? - Controversial interpretation

ALSO:

- Note for Guidance re Treated Articles

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 [...] it is covered by the definition of a biocidal product [...]. It is therefore irrelevant whether the biocidal function is primary or secondary.

- Why different from treated articles?
IMPORTANTLY, ALSO:

“A Masterbatch imported into the EU that will be used in the EU to confer a biocidal property or function to a mixture or an article shall be regarded as a biocidal product, even if it might confer non-biocidal functions as well.”

NEVERTHELESS:

“By considering the above elements, economic operators should be able to determine whether the masterbatch they may use fall into the scope of BPR and if so, shall be considered as biocidal products or not.”

HOW?
The “Masterbatch question”: Scenarios (1)

- **Is a Masterbatch incorporating an active substance a treated article?**

- Treated article: “..*treated with, or intentionally incorporates .. biocidal products*”
  - **Double intention:**
    - **First**, the **intention** to use the **active substance** in the biocidal product is required
    - **Second**, the **intention** to use this **biocidal product** to treat with or incorporate into an article is required
    - This means that the biocidal product (and hence the active substance) must have been **applied with the intention** of exerting a biocidal effect in the treated article itself.

- **As a Masterbatch** does not incorporate an active substance with the intention of exerting a biocidal effect in the Masterbatch itself, it is **not a treated article**
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"), i.e. it does not concern directly components of complex articles or intermediate forms which are not themselves placed on the EU market.

The intentional incorporation of a biocidal product in a component of an complex article seems to imply a beneficial effect for the finished article.

In applications where the incorporation of biocidal products into individual components of complex articles was merely in order to perform a specific biocidal function at that stage of the process, but without an intended function in the finished article as placed on the EU market should not be considered as a treated article.
The “Masterbatch question”: Scenarios (2)

- In which case is an article made of a resin which incorporated a Masterbatch of an active substance a Treated article?

Based on the above:

- In a Masterbatch the active substance is (normally) not added with the intention to control harmful organisms within the Masterbatch; hence a Masterbatch is (normally) not a biocidal product.

- If the Masterbatch is not a biocidal product, its incorporation into an article does not make it a Treated article.

- Potentially in conflict with the Commission Decision…
The impact of Treated articles definition on the Masterbatch question

- **Intention** of biocidal property in the *finished article* is the defining element

- **Border-line cases** / differing MS interpretations: *Binding implementing acts* from the Commission upon MS request

- **Future developments?**
Questions?

agergely@steptoe.com