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Masterbatches under the BPR: a riddle resolved?

Stakeholders have been asking the EU authorities for urgent clarification on the status of masterbatches since Echa's first Biocides Stakeholder Day in June 2013. In this expert article Dr. Anna Gergely and Darren Abrahams, of Steptoe & Johnson suggest that moment may have finally arrived.

The long interpretive discussions on the status of masterbatches and of treated articles share a common cause. There has been a tendency to lose sight of the purpose of the Biocidal Products Regulation (BPR) and view it in isolation from the rest of EU chemicals, health and safety law.

The aim of the BPR is to regulate those active substances and biocidal products that are used for intended biocidal effects and not to protect the health of people and the environment in the EU from potential unintended biocidal effects. There is a mass of EU legislation that addresses unintended effects, including REACH, product specific regimes, and worker and consumer protection laws.

The BPR is not designed to regulate a category of chemicals with certain inherent (biocidal) properties. Indeed, many biocidal active substances also have non-biocidal applications exploited on the commodity chemicals market.

Intention, intention, intention

Intention is a core notion in the definition of a biocidal product under the BPR Article 3(1)(a): "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".

Similarly, treated articles that are not biocidal products (where there is no primary biocidal function) are defined in Article 3(1)(l) as "any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products". It follows, that a treated article exists only where there is a *dual* biocidal intention. The intention that the biocidal product:

- in the form provided to the user, would have a biocidal effect; and
- is incorporated in (or used to treat) the treated article (and not merely present) to confer biocidal properties in the treated article itself.

Treated articles may also be mixtures, so the same set of considerations apply to a masterbatch mixture (whether in solid or liquid form) in deciding how it is regulated under the BPR.

What is a masterbatch?

Although widely used commercially, these "interim" products are not defined by the BPR. The 'Note for guidance on the application of provisions of the BPR on masterbatches' (CA-May15-Doc.6.2), provides a common definition:

"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."

For example, masterbatches are abundant in polymer production, to confer - among others - biocidal properties to final products. It is only the user of the masterbatch in the finished product who has the intention to exploit its biocidal property, hence the masterbatches only meet the definition of a biocidal product in this last stage of manufacturing.

This interpretation is supported not just by the legal definitions of the BPR, but also by very practical considerations. Masterbatches are tailored for specific downstream needs, so there is great variety in their actual composition. Accordingly, if all those masterbatches which contain active substances with intrinsic biocidal properties would be considered "biocidal products" (as some stakeholders have argued), a very large number of authorisations would be required for products which would never been used in their actual form for their biocidal effects. This would be all the more difficult to accept, given that, as interim products, efficacy testing "in the form as supplied to the user" would be meaningless, since the exploitation of biocidal properties only occurs at a subsequent stage, in a different form.

Is it a biocidal product, a treated article or a simple mixture?

As explained, whether the masterbatch of an active substance itself is a biocidal product falling under the BPR depends on its intended use:

- 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); however
- when the masterbatch is only used to manufacture a biocidal product, it should be considered a simple mixture. Also, an intermediate masterbatch intended for further processing is not a biocidal product.

On that basis, in a masterbatch a biocidal active substance may even 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.

Equally, a masterbatch does not incorporate an active substance with the intention of exerting a biocidal effect in the masterbatch itself, so it is not a treated article.

Companies will want to think carefully about what they communicate as regards information that could be misconstrued as indicating the presence of the required (dual) intentions.

Positive signs and next steps

The logic of the approach we have advocated for a long time and outlined above appears to have been accepted by the Commission. In its Implementing Decision (EU) 2015/411, of 11 March 2015, it concluded that for polymeric binders with QUATs (which themselves do not have an antimicrobial activity), marketed for being incorporated in paints to confer to the paint the biocidal function to destroy harmful organisms:

- the polymeric binders with the QUATs are not biocidal products because there is no intended biocidal function in that form; and
- the treated paint is a biocidal product because it generates an active substance with intended biocidal function.

This binding Decision is a welcome clarification, but the 'Note for Guidance' appears to establish a policy goal of ensuring that where an active substance is used for a biocidal intention, "at least once in the supply chain" there should be a biocidal product authorisation. For the reasons set out in this article, we consider

that this apparent willingness to ignore the dual intention requirement should be resisted, as it breaches the clear text of the BPR. In any event, there should not be an objective of ensuring "at least" one authorisation is made in the supply chain. At the very most there should be only one and even then only when the dual intention requirement is satisfied.

Companies will have to pick their battles and decide when to seek support for their interpretations, using the Article 3(3) mechanism to elicit binding (and challengeable) Implementing Decisions from the Commission. It seems likely that despite the welcome moves made to clarify the status of masterbatches, some hard cases will have to be examined by EU decision makers and possibly the courts.

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