Transitioning to the BPR: what will become of the Manual of Decisions?

Many borderline situations that were formerly "settled" in the Manual of Decisions will now have the provisions of the BPR applying to them. In this expert article, authors Indiana de Seze, Darren Abrahams, and Dr Anna Gergely, of law firm Steptoe & Johnson argue that to avoid confusion the MoD should be reviewed or repealed.

The Manual of Decisions and the need to review it

Prior to the adoption of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (BPR), the EU Commission and the Member States competent authorities had devised a series of questions and answers based on situations frequently raised by industry and on the application of Directive 98/8/EC (then in force) on biocidal products to borderline situations. These questions and answers, compiled in a so-called Manual of Decisions (MoD), provided guidance on how to implement the Directive to them.

Guidance, in EU law, is meant to provide persons who need to comply with legislation, insight as to how such legislation is to be implemented, by delivering concrete examples or situations in which the legislation applies. Guidance is not law: it is not binding on third parties, however, it binds the author(s) of the guidance, who need to abide by it. We note that Echa does not appear to be involved in the guidance-making process (between the Commission and Member States) and therefore is not formally bound by such guidance. However, in practice it may want to express acceptance of Commission and Member State guidance.

On 12-14 November 2014 at the 58th meeting of representatives of Member States Competent Authorities (CA) for the implementation of the BPR, it was discussed whether the MoD was still relevant in the framework of the BPR in force since 1 September 2013.

The Commission presented a paper at the 58th CA meeting which identified that some of the Q&As could be considered as either obsolete, because they had been addressed through legislation or ad hoc guidance, or potentially in conflict with the provisions of the BPR or a recent judgment of the European Court of Justice in the Söll case1 on the definition of biocidal products. In both cases, there was some relevance in addressing the status of these Q&As as still applicable or not.

The Commission asked the CA whether they could endorse a proposal consisting of considering the MoD as inapplicable when new guidance is published by the Commission.

It was further proposed that in case the new guidance would "revise" previous guidance which concluded that a product was not within the scope of the Directive, the concerned persons would be provided with an opportunity to submit a declaration of interest to notify the substance/product-type combination pursuant to Article 16(1)(a) of the Commission Delegated Regulation (EU) No 1062/2014 (the work programme).

[1] Case C-420/10: Judgment of the Court (Third Chamber) of 1 March 2012 (reference for a preliminary ruling from the Landgericht Hamburg — Germany) — Söll GmbH v Tetra GmbH (Placing on the market of biocidal products — Directive 98/8/EC — Article 2(1)(a) — Concept of 'biocidal products' — Product causing flocculation of harmful organisms without destroying or deterring them or rendering them harmless)

Three additional options were described as available for verifying the applicability of the BPR to a product not previously within the scope of the Directive, namely:

- for persons concerned, submit a request through the Echa helpdesk to check whether a different answer would be provided today under the BPR, or in the light of the *Söll* case;
- for Member States CAs, submit a request in accordance with Article 3(3) of the BPR, at their own initiative or upon request of a stakeholder, asking the Commission to clarify whether a specific product or group of products is a biocidal product or a treated article or neither; and
- for Member States, use the *HelpEx* tool to validate some of the Q&As, which may still be relevant, and which, once reconfirmed, could be made publicly available by Echa.

The draft minutes of the 58th CA meeting record that while several Member States indicated that they could support the approach proposed by the Commission and consider the MoD as inapplicable, several other Member States suggested keeping the MoD available with an appropriate disclaimer that the answers have to be read in context of the now repealed Directive. This is the solution which will be adopted until further reflection by the Commission on how to provide a better access to all the answers which will be provided through all the different avenues described above such as, CA meetings, Article 3(3) BPR, *HelpEx* and Echa guidance.

The relevance of a Manual of Decisions version 2.0

The industry should welcome a solution, yet to be finalised, consisting of a document or database compiling all the answers relating to the transition from the Directive to the BPR, and impacting products which were not considered biocidal products until 1 September 2013, as well as companies which legitimately placed them on the market without having to undergo product authorisation and/or active substance/product type approval processes.

Treated articles and *in situ* generated active substances are illustrative of both these situations. The Commission has prepared relevant new draft guidance in the form of papers endorsed, or to be endorsed, by the Member States at CA meetings. Although such guidance is welcome in principle, , it has revisited a number of issues, sometimes extending the provisions of the BPR and sometimes even contradicting them. Guidance cannot be lawfully applied if it conflicts with the underlying legal framework.

In situ generated active substances and their precursors

For instance, *in situ* generated active substances, which were not expressly covered by the Directive but are now covered by the BPR, as well as the substances they are generated from (albeit not covered by the *Söll* case definition of biocidal products), present a number of uncertainties. With regard to the obligations of industry under the transitional provisions of the Regulation: Article 95 requires that suppliers of active substances and relevant substances (including substances generating active substances) must be listed by 1 September 2015, while Article 93 of the BPR requires the persons who place on the market biocidal products (including substances generating active substances) newly in the scope of the BPR to submit a dossier by 1 June 2016. Clearly those two dates are conflicting.

Yet, a paper presented by the Commission at the same CA meeting (CA-Nov14-Doc.4.1) concludes that for those active substance/precursor/product type combinations which were already in the review programme, the earlier date of 1 September 2015 applies, thus creating confusion for those producers of precursors who would be entitled to remain on the market lawfully by submitting a dossier by the later date. Not to mention that some of the *in situ* generated active substances already included in the review programme are being redefined to extend to situations which were not within the scope of the Directive. By being absorbed into the review programme, these situations will lose the benefit of the transitional provisions of the BPR.

Treated articles and food contact materials

For treated articles and food contact materials, it is acknowledged that most answers in the MoD are to be revisited in view of the specific provisions of Article 58 of the BPR, and the entry of food contact materials within the scope of the BPR under product type four. FAQs have been drawn up by the Commission on treated articles (CA-Nov14-Doc.6.1) which seek to address repetitions and contradictions as well as specific examples of articles/products as compared to the MoD. Some conclusions under the MoD have been maintained (processing aids, articles with an intended external effect) while others are clearly contradicted by the text of the BPR, hence, have been modified, creating some potential confusion.

On-site formulation and use of biocidal products

Q&As for on-site formulation and use of biocidal products will also need to be revisited, since the use of biocidal products is regulated by the BPR (Article 17). Draft guidance has been prepared in the form of a note on the Concepts of placing and making available on the market in the context of Regulation (EU) No 528/2012 (CA-Nov14-Doc.7.4), which adds to the Q&As on treated articles, determining the use and storage of a product.

Conclusion

Whilst mostly obsolete in view of the adoption of the BPR, in order to avoid any confusion in the transitional period, the Manual of Decisions should either be repealed or be converted into a new document, incorporating the decisions which remain valid under the new rules of the BPR, but incorporating latest endorsed guidance, for an effective implementation of the BPR.

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