



Label provision for treated articles under the Biocidal Products Regulation (BPR)

Biocidal products in the EU are currently regulated by the Biocidal Products Directive (BPD). The Commission has proposed a new regulation, the Biocidal Products Regulation (BPR), to replace the BPD. The final text of BPR was approved by the European Parliament on 19th February. The BPR comes into force 20 days after publication, in the summer of 2012, and will apply from September 1st, 2013.

The BPR introduces a new definition and related label requirements for “Treated Articles”. According to Art. 3.1(I), “treated article” means any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products. Enzyme products which are treated with biocidal product(s) or contain biocidal products, e.g. in-can preservatives, are treated articles. Treated articles may only be treated with, or contain approved active substances (Art 58-2).

Technical enzyme treated articles are in the scope of the BPR, however Food and Feed enzyme treated articles ¹ are exempt (Art. 2.2(d) and (f)). Although most enzyme products are used as processing aids they are not exempted by Art. 2.5.²

Label information should be provided if a treated article itself has a biocidal claim or if the conditions associated with the approval of the active substance(s) requires labeling (Art. 58-3). The latter part refers specifically to the possibility of contact with humans or release to the environment. This would suggest that in-can preservatives which are added intentionally to enzyme products and function as preservatives shall be listed on labels from September 1st, 2013. This should apply for both enzyme products manufactured in

¹ within the definition of point (b) of Article 3(2) of Regulation (EC) No 1333/2008 or point (h) of Article 2(2) of Regulation (EC) No 1831/2003

² The Art. 2.5 exemption of processing aids is only for “biocidal products when used as processing aids”, and enzyme products themselves are not biocidal products.

the EU and imported from non-EU countries. However the reference to “conditions associated with the approval of the active substance(s)” indicate that these labeling requirements should be specifically mentioned in active substance approval decisions in future. These conditional requirements are still unclear to us and we have to wait for further clarification or guidance from e.g. ECHA before labeling information is needed routinely.

There are transition measures for treated articles which contain biocides (active substances) which are not approved under BPD/BPR and which are already available on the market at the time the BPR comes into force. Such treated articles may remain on the market, provided that an application for approval of the active substance in relation to its use has been submitted at the latest September 1st 2016. The treated article cannot be placed on the market anymore from 180 days after a decision not to approve the active substance has been made (Art. 94).

Recommendation

According to the current text of the BPR, it can be interpreted that in-can preservatives added intentionally to technical enzyme products may need to be listed on labels from September 1st, 2013. After the transition period technical enzyme products shall only be treated and preserved with active substances that are approved or still undergoing evaluation for approval.

Disclaimer:

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